PEGSummit.com

FINAL DAYS TO REGISTER

2021 CONFERENCE
PROGRAMS

- ENGINEERING
- ONCOLOGY
- BISPECIFIC ANTIBODIES
- IMMUNOTHERAPY
- EXPRESSION
- ANALYTICAL
- IMMUNOGENICITY
- COVID INTERVENTIONS (NEW)
- SC SHORT COURSES

Sponsor & Exhibit Opportunities

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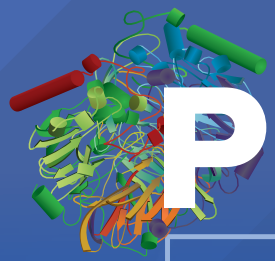

17th Annual

PEGS BOSTON

VIRTUAL CONFERENCE & EXPO

The Essential Protein Engineering and Cell Therapy Summit

MAY 11-13, 2021 | EDT

INTERACTIVE NETWORKING
live Q&A, roundtables, chat with exhibitors, sponsors, and fellow delegates

RESEARCH POSTERS
engage with researchers presenting the latest developments in biotherapeutics R&D

INSPIRING KEYNOTE PRESENTATIONS
from world-renowned experts and visionaries

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VIRTUAL CONFERENCE & EXPO | MAY 11-13, 2021 | EDT

PEGS BOSTON

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

For more than 15 years, the **PEGS Boston Summit** has been the premier networking and professional development event for biotherapeutics drug development research and collaboration. In this time of unprecedented change, we are excited to bring you a fully integrated virtual event - enabling the global community to stay connected and receive the same quality content and networking experience you have come to expect.

Join your peers and colleagues from around the world to share insights, case studies, cutting-edge research, and form collaborations to advance biotherapeutics development.

2021 CONFERENCE PROGRAMS

CONFERENCE AT-A-GLANCE

PEGSBOSTON | MAY 11-13, 2021 | EDT

STAY CONNECTED @PEGSBoston #PEGS21

2021 PROGRAMS

	TUESDAY-WEDNESDAY AM (MAY 11-12)	WEDNESDAY PM-THURSDAY (MAY 12-13)
ENGINEERING	Display of Biologics	Engineering Antibodies
ONCOLOGY	Antibodies for Cancer Therapy	Driving Clinical Success in Antibody-Drug Conjugates
BISPECIFIC ANTIBODIES	Advancing Bispecific Antibodies and Combination Therapy to the Clinic	Engineering Bispecific Antibodies
IMMUNOTHERAPY	Improving Immunotherapy Efficacy and Safety	CAR Ts, TCRs and TILs
EXPRESSION	Difficult-to-Express Proteins	Optimizing Protein Expression
ANALYTICAL	Characterization for Novel Biotherapeutics	Biophysical Methods
IMMUNOGENICITY	Training SEMINARS Introduction to Immunogenicity	Immunogenicity Assessment and Management
COVID INTERVENTIONS (NEW)	Therapeutic Interventions for COVID-19	Accelerating Vaccine Development for COVID-19
SHORT COURSES	SC1: CAR T Cell Therapy From A-Z	SC3: Developability of Bispecific Antibodies: Formats and Applications
	SC2: Introduction to Gene Therapy Products Manufacturing and Analytics	

2021 SPONSORS

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fusionantibodies
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PerkinElmer For the Better
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RETROGENIX SPOTTING YOUR TARGET.
RheoSense Simply Precise
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SELEXIS
Sphere Fluidics
TetraGenetics
TWIST BIOSCIENCE
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CHI VIRTUAL EVENTS GET RAVE REVIEWS

"Given the challenging logistics and infrastructure for a virtual conference during the COVID pandemic, this was an exceptional experience, and I was impressed with the efforts by the CHI staff and their ability to pivot to and host an impactful and connecting virtual conference."

Charles Wartchow, Principal Investigator, Novartis Institutes for BioMedical Research

"**A very well-structured virtual conference that met the participants' requirements whilst creating a stimulating environment for networking.**"

Shahid Uddin, Director, Drug Product, Formulation & Stability, Immunocore

"Let me take this opportunity to congratulate all of you for a very successful digital version of CHI's Drug Discovery Chemistry! Viruses can't stop science nor our willingness to continue sharing the great work we scientists do. Thank you for your unwavering support and commitment to excellence!"

Maricel Torrent, Principal Research Scientist, AbbVie

"I was humbled to be there (Virtually) to share my knowledge and expertise. It was a great experience and I'm glad to be part of the meeting and was able to really catch up with my industry peers."

Dhanuka Wasalathanthri, PhD, Senior Scientist, Biologics Process Development, Bristol Myers Squibb Co.

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Healthtech.com

17th Annual
PEGS BOSTON
VIRTUAL CONFERENCE & EXPO
MAY 11-13, 2021 | EDT | **PegSummit.com**

Register Today

TUESDAY, MAY 11 | 11:30 AM

The Coming of Age of *De Novo* Protein Design

DAVID BAKER, PhD

Henrietta & Aubrey David Endowed Professor, Biochemistry, University of Washington

Proteins mediate the critical processes of life and beautifully solve the challenges faced during the evolution of modern organisms. Our goal is to design a new generation of proteins that address current day problems not faced during evolution. In contrast to traditional protein engineering efforts, which have focused on modifying naturally occurring proteins, we design new proteins from scratch based on Anfinsen's principle that proteins fold to their global free energy minimum. We compute amino acid sequences predicted to fold into proteins with new structures and functions, produce synthetic genes encoding these sequences, and characterize them experimentally. I will describe the *de novo* design of fluorescent proteins, membrane penetrating macrocycles, transmembrane protein channels, allosteric proteins that carry out logic operations, and self-assembling nanomaterials and polyhedra.
I will also discuss the application of these methods to COVID-19 challenges.

THURSDAY, MAY 13 | 11:30 AM

LIVE PLENARY PANEL:

Antibody and Vaccine Development for COVID-19

PANEL MODERATOR:
Erica Ollmann Saphire, PhD, Professor, La Jolla Institute for Immunology

PANELISTS:

Lakshmi Krishnan, PhD, A/Vice-President, Life Sciences, National Research Council Canada, Government of Canada

Peter W. Marks, MD, PhD, Director, FDA CBER

Peter Hotez, MD, PhD, FASTMH, FAAP, Dean, National School of Tropical Medicine; Professor, Departments of Pediatrics, Molecular Virology & Microbiology; Co-Head, Section of Pediatric Tropical Medicine; Health Policy Scholar, Baylor College of Medicine

YOUNG SCIENTIST KEYNOTE **WEDNESDAY, MAY 12 | 11:30 AM**

Cryo-Electron Microscopy Structures of Spike Glycoproteins Suggest Pan-Coronavirus Antiviral Strategy

CHRISTINE TOELZER

Research Associate, University of Bristol, United Kingdom

We research antivirals to combat present and future coronavirus pandemics. We discovered linoleic acid bound to a hydrophobic pocket in the Cryo-EM structure of the SARS-CoV-2 Spike glycoprotein. Ligand binding locked the protein in a compact closed conformation. Conservation of key AA residues suggested a similar pocket exists in other pathogenic coronaviruses.

TUESDAY, MAY 11 3:30-6:00 PM

SC1: CAR T CELL THERAPY FROM A-Z

Instructor:
Tara Arvedson, PhD, Executive Director, Oncology Research, Amgen, Inc.

This course will provide an overview of the history of the CAR T cell platform including early successes and failures. It will review learnings from the non-clinical and clinical evaluation of CAR T cells in hematologic malignancies and solid tumors. It will discuss challenges encountered with the current CAR T cell formats and approaches to address these challenges followed by discussion of the next generation CAR T cells including technical improvements and therapeutic opportunities.

SC2: INTRODUCTION TO GENE THERAPY PRODUCTS MANUFACTURING AND ANALYTICS

Instructors:
Claire Davies, PhD, Associate Vice President, Bioanalytics, Sanofi
Scott Dooley, Scientist, Analytical Development, Sanofi

This short course introduces concepts that can be used to facilitate CMC development for gene therapy products. The instructors will review regulatory guidance and present phase-appropriate control strategies. Several CMC challenges unique to this modality will also be discussed, along with different manufacturing platforms. The workshop will include an interactive session on developing an integrated control strategy.

WEDNESDAY, MAY 12 3:30-6:00 PM

SC3: DEVELOPABILITY OF BISPECIFIC ANTIBODIES: FORMATS AND APPLICATIONS

Instructor:
Nimish Gera, PhD, Head, 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.

PRESENT A **VIRTUAL POSTER**

SAVE $50*

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the virtual poster sessions. To ensure your poster presentation is included in the conference materials, your full submission must be received, and your registration paid in full by April 2, 2021.

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

Virtual scientific poster presentation materials will include:

- Poster Title
- Text-only Abstract. It can be an in-depth, one-page abstract, or just a short description.
- 3-5 minute voice-over PowerPoint presentation. You may substitute the PowerPoint with a one-page, static PDF of your poster.

** Product and Service providers do not qualify for the poster discount.*

ENGINEERING STREAM

Advancements in Discovering and Optimizing Novel Biotherapeutics

The COVID-19 pandemic resulted in a surge of activity by research groups working toward the rapid discovery and development of treatments and vaccines with attributes allowing global-scale production and deployment. With this as a foundation, the PEGS Engineering Stream examines the state of the science in biologics R&D, including smarter and higher throughput screening methods, increased role of AI and machine learning, novel constructs and impact of new understandings of immunology on protein engineering. Plan to attend and learn why this has become the industry's leading event in biotherapeutics.

2021
ENGINEERING STREAM
CONFERENCES

May 11-12

Display of Biologics

AGENDA

May 12-13

Engineering Antibodies

AGENDA

PEGSBOSTON
CONFERENCE STREAMS

ENGINEERING | ONCOLOGY | BISPECIFIC ANTIBODIES | IMMUNOTHERAPY
EXPRESSION | ANALYTICAL | IMMUNOGENICITY | COVID INTERVENTIONS

MAY 11-12, 2021 | 23nd Annual

DISPLAY OF BIOLOGICS

Designing Antibody Drugs of the Future

TUESDAY, MAY 11

ANALYSIS OF REPERTOIRES

9:00 am KEYNOTE PRESENTATION: Analysis of B Cell Receptor Repertoires in Health and Disease

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

Understanding the convergence of B cell receptors between cohorts of patients who show resilience to certain types of cancer or to neurodegenerative disease is a potential route to providing both an insight into disease biology and putative leads for therapeutic antibody development. Alchemab's approach to BCR repertoire analysis in different disease settings will be presented with some examples of how this has informed our understanding of disease progression.

9:20 New Facets of Human Humoral Immunity and Antibody Effector Functions

George Georgiou, PhD, Cockrell Centennial Chair & Professor, Molecular Biosciences & Chemical Engineering, University of Texas, Austin

This presentation will outline our recent findings on the molecular composition of the serological repertoire and on the role of Fc receptors on effector functions.

9:40 One by One – The Quantitative Assessment of the Secreted IgG Repertoire after Recall to Evaluate the Quality of Immunizations

Klaus Eyer, PhD, Professor, Functional Immune Repertoire Analysis, ETH Zurich

In this presentation, I will give a short introduction into the technology that enables to perform these measures, 'DropMap,' and show some of its applications within our research projects. In particular, the talk focuses on how single-antibody resolution is used to quantitatively study immunizations in my group; and how we use multidimensional assays and functional readouts to characterize the secreted antibody repertoire.

10:00 Writing the Future of Biologics using the Twist Biopharma Library of Libraries

Aaron Sato, Ph.D., Chief Scientific Officer, Biopharma, Twist Bioscience

Utilizing its proprietary DNA technology to write synthetic libraries, Twist Biopharma provides end-to-end antibody discovery libraries including both highly diverse synthetic naïve antibody phage display libraries and target class specific antibody phage display libraries against difficult-to-drug targets. In this talk, Aaron, will present several POC data on each member of their Library of Libraries. For some of the targets, the power of selecting multiple libraries against each target will be highlighted.

10:20 Antibody based prophylactic and therapeutic strategies against SARS-CoV-2

Mart Ustav Jr, Dr, CSO, Icosagen Cell Factory OÜ

In this talk we will highlight Icosagen's antibody developments against SARS-CoV-2 and demonstrate the efficacy of alternative antibody isotypes to viral neutralization, including potential viral variants. We demonstrate *in vivo* efficacy of these approaches that have implications for more effective delivery of neutralizing antibodies to the primary sites of infection.

10:50 LIVE PANEL DISCUSSION: Analysis of Repertoires

Moderator: E. Sally Ward, PhD, Director, Translational Immunology; Professor, Molecular Immunology, Centre for Cancer Immunology, University of Southampton
Panelists:
Jane K. Osbourn, PhD, CSO, Alchemab Therapeutics Ltd.
George Georgiou, PhD, Cockrell Centennial Chair & Professor, Molecular Biosciences & Chemical Engineering, University of Texas, Austin
Klaus Eyer, PhD, Professor, Functional Immune Repertoire Analysis, ETH Zurich
Mart Ustav Jr, Dr, CSO, Icosagen Cell Factory OÜ
Aaron Sato, Ph.D., Chief Scientific Officer, Biopharma, Twist Bioscience

11:10 Session Break - View Our Virtual Exhibit Hall

11:10 ASK THE EXPERT with Svar Life Science

Michael G. Tovey, Ph.D, Chief Scientific Advisor of Svar Life Science France, Svar Life Science

Svar´s Expert session will focus on AAV mediated gene therapy and potential neutralizing antibody response to AAV vectors. We know the importance of precisely quantify both the neutralizing antibody response prior to treatment, and the neutralizing antibody response to the recombinant AAV vector following treatment. Talk to us about how our highly sensitive reporter-gene assays are used for the quantification of NAbs to recombinant AAV vectors with different capsid specificities.

PLENARY KEYNOTE ADDRESS

11:25 Plenary Keynote Introduction

Jennifer R. Cochran, PhD, Shriram Chair & Professor, Bioengineering & Chemical Engineering, Stanford University

11:30 KEYNOTE PRESENTATION: The Coming of Age of *de Novo* Protein Design

David A. Baker, PhD, Henrietta & Aubrey David Endowed Professor, Biochemistry, University of Washington

I will describe the *de novo* design of fluorescent proteins, membrane penetrating macrocycles, transmembrane protein channels, allosteric proteins that carry out logic operations, and self-assembling nanomaterials and polyhedra. I will also discuss the application of these methods to COVID-19 challenges.

12:00 pm LIVE: Q&A with Audience

Moderator: Jennifer R. Cochran, PhD, Shriram Chair & Professor, Bioengineering & Chemical Engineering, Stanford University
Panelists:
David A. Baker, PhD, Henrietta & Aubrey David Endowed Professor, Biochemistry, University of Washington

12:10 Session Break - View Our Virtual Exhibit Hall

BREAKOUT DISCUSSIONS

12:20 Problem Solving Discussions

Join your colleagues and fellow delegates for a focused, informal discussion moderated by a member of our speaking faculty. A small group format allows participants to meet potential collaborators, share examples from their own work and discuss ideas with peers. See website for a full list of topics.

TABLE: Engineering Synthetic T Cell Receptors

Sai Reddy, PhD, Associate Professor, Systems and Synthetic Immunology, ETH Zurich, Switzerland

- Rapid discovery of natural TCRs
- Synthetic TCRs, how to make them safe from cross-reactivity
- What possibilities are there for soluble TCRs
- How to determine TCR specificity at high-throughput

1:00 Session Break - View Our Virtual Exhibit Hall

PROTEIN DESIGN AND ENGINEERING: BACK TO BASICS

1:10 ***De Novo*** **Design of a Self-Assembling Superantigen: A Potential Cancer Immunotherapy Via Controlled T Cell Activation**

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

To improve the safety profile of an immunotherapy, an on/off switch, along with the ability to locally activate T cells, can provide the much-needed control. Here, we leverage the unique T cell activating capabilities of superantigens and use computational protein design methods to build an AND gate logic via self-assembly.

1:30 **Sensors and New Shapes: Computational Design of New Molecular Geometries and Ligand-Controlled Functions**

Tanja Kortemme, PhD, Professor, Bioengineering & Therapeutic Sciences, University of California, San Francisco

Despite much progress in computational protein design, significant challenges remain in the complexity of protein geometries and functions that can be designed at present. I will discuss our recent progress with (i) reshaping of protein conformations for reprogrammed functions, (ii) engineering small molecule binding sites *de novo* to detect and respond to new small molecule signals, and (iii) controlling protein shapes to create fold families for new functions.

COMPUTATIONAL PROTEIN ENGINEERING AND DESIGN

1:50 **KEYNOTE PRESENTATION: Computational Design of Binding Proteins**

William F. DeGrado, PhD, Professor, Pharmaceutical Chemistry; Investigator, Cardiovascular Research Institute, University of California, San Francisco

This talk will focus on new approaches to *de novo* computational design of proteins that bind metal ions, cofactors and small molecule ligands.

2:10 **Next-Generation Repertoire Sequencing for Mining Single Domain Antibodies**

Stefano Bonissone, PhD, CSO, Digital Proteomics

Next-generation sequencing of antibody repertoires has provided new insights into natural immune response. The correlation between the B-cell receptor repertoire and the serological antibody repertoire, however, has only been analyzed in a small number of studies. In this talk we will discuss the use of serum antibodies to guide antibody discovery in an immunized llama. Further, we use next-generation sequencing to mine the clonal lineage of serum-identified antibodies.

2:40 **LIVE PANEL DISCUSSION: Computational Protein Design and Engineering**

Co-Moderators:
K. Dane Wittrup, PhD, CP Dubbs Professor, Chemical Engineering & Bioengineering, Massachusetts Institute of Technology
Jennifer R. Cochran, PhD, Shriram Chair & Professor, Bioengineering & Chemical Engineering, Stanford University
Panelists:
Possu Huang, PhD, Assistant Professor, Bioengineering, Stanford University
Tanja Kortemme, PhD, Professor, Bioengineering & Therapeutic Sciences, University of California, San Francisco
William F. DeGrado, PhD, Professor, Pharmaceutical Chemistry; Investigator, Cardiovascular Research Institute, University of California, San Francisco
Stefano Bonissone, PhD, CSO, Digital Proteomics

3:00 PEGS Connects - View Our Virtual Exhibit Hall

NOVEL PLATFORMS FOR SYSTEMS LEVEL SCREENING

3:10 **High-Throughput Sorting of Single Cells Based on Secreted Products Using Lab on a Particle Technology**

Dino DiCarlo, PhD, Professor, Bioengineering, University of California, Los Angeles

I will discuss nanovial technology that enables the isolation of individual cells in uniform drops with simple mixing operations massively in parallel, the accumulation of secreted products at high concentrations, and the downstream sorting of cells based on their secretions using standard FACS systems. This approach promises to democratize the ability to discover and manufacture drugs and cell therapies.

3:30 **Engineering Synthetic T Cell Receptors for Enhanced Potency and Specificity**

Sai Reddy, PhD, Associate Professor, Systems and Synthetic Immunology, ETH Zurich, Switzerland

We engineer synthetic TCRs with enhanced activity and high specificity for the MAGE-A3 tumor antigen with no detectable cross-reactivity. High- throughput engineering of synthetic TCRs on the basis of their activity enables the development of more potent and safe therapeutic candidates.

3:50 **Diversity-Oriented Approaches to Develop Novel CAR Signaling Programs**

Michael E. Birnbaum, PhD, Assistant Professor, Biological Engineering, Massachusetts Institute of Technology

Clinical successes for engineered T cell therapies has led to efforts to expand these treatments to new applications. Many attempts to develop these treatments rely upon inherently low-throughput methods. We have developed a selection-based approach to identify novel CAR intracellular domain combinations based upon their induced cell phenotypes. Initial applications of this approach to CD19-targeting CARs show novel signaling compositions and biological functions that were previously not observed.

4:20 **Live Panel Discussion: Novel Platforms for Systems Level Screening**

Moderator: Jamie B. Spangler, PhD, Assistant Professor, Biomedical Engineering and Chemical & Biomolecular Engineering, Johns Hopkins University
Panelists:
Dino DiCarlo, PhD, Professor, Bioengineering, University of California, Los Angeles
Sai Reddy, PhD, Associate Professor, Systems and Synthetic Immunology, ETH Zurich, Switzerland
Michael E. Birnbaum, PhD, Assistant Professor, Biological Engineering, Massachusetts Institute of Technology

4:40 Close of Day One

3:30 **SC1: CAR T Cell Therapy from A-Z SC2: Introduction to Gene Therapy Products Manufacturing and Analytics**

Separate registration required. See short course page for details.

WEDNESDAY, MAY 12

GENERATING ANTIBODIES AGAINST COVID-19 BY DIFFERENT RECOMBINANT METHODS

9:00 am **The Greatest Competition in Antibody History: A Naïve Library Directly Delivering Antibodies As Potent As Immune Sources**

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

The SARS-CoV-2 pandemic resulted in an extraordinary worldwide unplanned experiment, in which numerous groups generated antibodies against a single target: CoV-2 spike. The most potent were generated from convalescent patients, with naïve libraries yielding significantly worse antibodies. Here we show ultra-potent (IC50 <2ng/ml) human neutralizing antibodies can be generated directly from an innovative naïve antibody library with affinities, developability properties and neutralization activities comparable to the best from hyperimmune sources.

9:20 **Human Monoclonal Antibodies for Emerging Infections**

James E. Crowe Jr., MD, Ann Scott Carell Chair & Professor & Director, Vaccine Center, Vanderbilt University Medical Center

Epidemics and pandemics with RNA viruses are occurring at an accelerating pace. We have embarked on a long term project to discover best-in-class human monoclonal antibodies for the 100 most likely epidemic viruses, a project called AHEAD100.

9:40 Rapid Selection, Characterization and Clinical Development of Fully-Human Antibodies against Emerging Infectious Diseases

Christos Kyratsous, PhD, Vice President, Research, Infectious Diseases & Viral Vector Tech, Regeneron Pharmaceuticals Inc.

Antibodies have become important in treating infectious diseases. We recently developed a triple antibody cocktail against Ebola virus, the first FDA approved therapy for this indication. Now, we describe the generation and characterization of an antibody cocktail against SARS-CoV-2. Early clinical data confirmed its antiviral activity and demonstrated clinical benefit by significantly reducing medical visits of symptomatic ambulatory patients. Our cocktail received Emergency Use Authorization, while clinical testing is continuing.

10:00 Fast-Track Generation of SARS-CoV-2 TrailBlazer Antibodies

Francisco Ylera, Ph.D., R&D Team Leader, New Technologies, Bio-Rad Laboratories Inc.

We developed recombinant antibodies against SARS-CoV-2 using our fast-track TrailBlazer Antibody service. The process combined antibody phage display and our new modular antibody assembly platform based on SpyTag-SpyCatcher technology, which allows the rapid construction of antibodies in various formats from pre-produced protein modules. Here we explain how the combination of these powerful technologies reduced the time from antigen receipt to shipment of synthetic IgGs to just 4 weeks.

10:20 OptiMAL: A Novel Library Design and Mammalian Display Selection Platform

Richard Buick, Dr, CTO, Fusion Antibodies

Currently in development, OptiMAL® is Fusion's new mammalian antibody library – a discovery platform yielding fully human antibodies.

OptiMAL® is for clients looking to streamline the discovery and preclinical optimization of novel antibodies. Incorporating Fusion Antibodies' proprietary protein engineering technologies, the library eliminates the need for platform switching and reformatting common with other approaches. The output from OptiMAL® is a fully-human antibody with no need for further humanisation.

10:50 LIVE PANEL DISCUSSION: Generating Antibodies Against COVID-19 by Different Recombinant Methods

Moderator: Andrew R.M. Bradbury, PhD, CSO, Specifica, Inc.
Panelists:
James E. Crowe Jr., MD, Ann Scott Carell Chair & Professor & Director, Vaccine Center, Vanderbilt University Medical Center
Christos Kyratsous, PhD, Vice President, Research, Infectious Diseases & Viral Vector Tech, Regeneron Pharmaceuticals Inc.
Dimiter Dimitrov, PhD, Professor and Director, Center for Antibody Therapeutics, University of Pittsburgh; Executive Vice President and CSO, Abound Bio
Richard Buick, Dr, CTO, Fusion Antibodies
Dominic Esposito, Dr., Director, Protein Expression Laboratory, Frederick National Laboratory for Cancer Research
Francisco Ylera, Ph.D., R&D Team Leader, New Technologies, Bio-Rad Laboratories Inc.

11:10 Session Break - View Our Virtual Exhibit Hall

11:10 CO-PRESENTATION: ASK THE EXPERT with SCIEX

Matt Stone, Biologics Workflow Specialist, SCIEX
Mukesh Malik, Sr. Application Scientist, SCIEX

Join SCIEX analytical technology experts Matthew Stone and Mukesh Malik during an interactive Q&A session to discuss analytical development and optimization of capillary electrophoresis and liquid chromatography-mass spectrometry based methods for protein characterization and quantification. Exciting topics covered include mAbs and mAb variants, cell and gene therapy, vaccines and more!

YOUNG SCIENTIST KEYNOTE

11:25 Young Scientist Keynote Introduction

Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute

11:30 KEYNOTE PRESENTATION: Cryo-Electron Microscopy Structures of Spike Glycoproteins Suggest Pan-Coronavirus Antiviral Strategy

Christine Toelzer, Research Associate, University of Bristol, United Kingdom

We research antivirals to combat present and future coronavirus pandemics. We discovered linoleic acid bound to a hydrophobic pocket in the Cryo-EM structure of the SARS-CoV-2 Spike glycoprotein. Ligand binding locked the protein in a compact closed conformation. Conservation of key AA residues suggested a similar pocket exists in other pathogenic coronaviruses.

12:00 pm Live: Q&A with Young Scientist Keynote

Moderator: Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute
Panelists:
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

12:10 Session Break - View Our Virtual Exhibit Hall

1:00 Close of Display of Biologics Conference

3:30 SC3: Developability of Bispecific Antibodies: Formats and Applications

Separate registration required. See short course page for details.

MAY 12-13, 2021 | 22nd Annual

ENGINEERING ANTIBODIES

New Science and Technologies for the Discovery and Engineering of Next Generation Biotherapeutics

WEDNESDAY, MAY 12

YOUNG SCIENTIST KEYNOTE

11:25 Young Scientist Keynote Introduction
Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute

11:30 KEYNOTE PRESENTATION: Cryo-Electron Microscopy Structures of Spike Glycoproteins Suggest Pan-Coronavirus Antiviral Strategy
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

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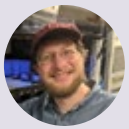
12:00 pm Live: Q&A with Young Scientist Keynote
Moderator: Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute
Panelists:
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

12:10 Session Break - View Our Virtual Exhibit Hall

COMPUTATIONAL PROTEIN DESIGN



1:10 KEYNOTE PRESENTATION: Engineering Antibodies Using Rosetta Antibody Design
Jared Adolf-Bryfogle, PhD, Principal Scientist, Protein Design Laboratory, Institute for Protein Innovation

Despite rapid progress in protein modeling and design, computational antibody design remains a difficult challenge. We created a generalized framework for computational antibody design within the Rosetta Software Suite. We utilize novel structural bioinformatics-based techniques that comprise all known antibody structure space to create and experimentally validate the RAbD antibody design software. Recently, we used RosettaAntibodyDesign (RAbD) to redesign three different SARS-CoV-1 antibodies to successfully bind SARS-CoV-2.

1:30 Improving the Drug-Like Properties of Affinity-Matured Antibodies via BioQSPR
Christopher Negron, PhD, Senior Scientist, Antibody Modeling, AbbVie

Computational chemists have long used quantitative structure-property relationships (QSPR) to elucidate design strategies to improve the drug-like properties of small-molecule therapeutics. However, duplicating such efforts in the context of biologics modalities remains challenging. In this presentation, two case studies describe the application of QSPR in the context of biologics drug discovery. In both cases, the QSPR methodology notably improved the drug-like properties found in both sets of affinity-matured antibodies.

RAPID DISCOVERY AND DEVELOPMENT DURING THE COVID-19 PANDEMIC

1:50 Bivalent Binding of a Fully Human IgG to the SARS-CoV-2 Spike Proteins Reveals Mechanisms of Potent Neutralization
Charles S. Craik, PhD, Professor, Departments of Pharmaceutical Chemistry, Pharmacology, and Biochemistry/Biophysics, University of California San Francisco

A mechanism-based biopanning strategy that specifically selects for antibodies that interfere with the interaction between the the SARS-CoV-2 Spike protein and ACE2 was used to identify antibodies that potently block ACE2 binding, yet exhibit divergent neutralization efficacy against live virus and in reconstituted human nasal and bronchial epithelium models. Cryo-EM structures of three different Spike-antibody complexes reveal distinct binding modes that alter the functional cycle of Spike conformations.

2:10 Rapid Development of Multivalent Anti-COVID-19 Antibodies
Sachdev Sidhu, PhD, Professor, Molecular Genetics, University of Toronto, Canada

We used protein engineering to develop tetravalent synthetic neutralizing antibodies for SARS-CoV-2. We show that these antibodies can be produced at large scale and possess stability and specificity comparable to approved antibody drugs. The best antibody targets the host receptor binding site of the virus spike protein, and thus, its tetravalent version can block virus infection with a potency that far exceeds that of the bivalent IgG.

2:30 Combating COVID-19: Identifying a Potential Drug Candidate for Human Testing in 90 Days
Bo Barnhart, PhD, Scientific Director, AbCellera

In three weeks, AbCellera discovered, characterized and selected hundreds of antibodies against SARS-CoV-2 from one of the first U.S. patients to recover from COVID-19. AbCellera's technology stack combines AI-assisted high-throughput single B cell screening with immune repertoire profiling of natural immune responses. Bioinformatic analysis of the resulting panels of antibodies allowed for the rapid characterization of neutralizing antibodies and the identification of therapeutic lead candidates including bamlanivimab.

2:50 Session Break - View Our Virtual Exhibit Hall

3:00 LIVE PANEL DISCUSSION: Integrating Computational and Experimental Methods for COVID Research
Moderator: Charles S. Craik, PhD, Professor, Departments of Pharmaceutical Chemistry, Pharmacology, and Biochemistry/Biophysics, University of California San Francisco
Panelists:
Jared Adolf-Bryfogle, PhD, Principal Scientist, Protein Design Laboratory, Institute for Protein Innovation
Deborah S. Marks, PhD, Associate Professor, Systems Biology, Harvard Medical School
Christopher Negron, PhD, Senior Scientist, Antibody Modeling, AbbVie
Sachdev Sidhu, PhD, Professor, Molecular Genetics, University of Toronto, Canada
Bo Barnhart, PhD, Scientific Director, AbCellera

3:20 PEGS Connects - View Our Virtual Exhibit Hall

3:30 SC3: Developability of Bispecific Antibodies: Formats and Applications
Separate registration required. See short course page for details.

4:00 Close of Day

THURSDAY, MAY 13

DISCOVERY FOR CHALLENGING TARGETS AND INDICATIONS

9:00 am Anti-GD2 mAbs
Stéphane Birklé, PhD, Professor, Pharmaceutical and Biological Sciences, University of Nantes, France

Target selection is a key feature in cancer immunotherapy. In this respect, gangliosides, a broad family of structurally related glycolipids, represent potential targets based on their higher abundance in tumors when compared with the matched normal tissues. This presentation will discuss the relevance of O-acetyl-GD2 as a novel target and presents the available preclinical data of O-acetyl-GD2-specific immunotherapies.

9:20 Novel Antibody Engineering to Improve Therapeutic Index of Antibody Targeting Solid Tumors and Its Therapeutic Application

Naoka Hironiwa, Senior Scientist, Chugai Pharmaceutical Co., Ltd., Japan

One of the remaining issues of antibody therapeutics is on-target, but off-tumor, toxicity induced by binding to target antigens expressed in normal tissues. To overcome this problem, we have established novel antibody engineering to enable antibody binding to the antigen selectively at tumor site but not at normal tissues. In this presentation the mechanism of selective binding and its application onto therapeutics will be discussed.

9:40 D Domains: A *de novo* Scaffold for the Development of Targeted Therapeutics

David LaFleur, Senior Director Discovery, Research & Translational Sciences, Arcellx Inc.

Built on *de novo* designed three-helix bundle protein, D domains constitute a robust targeting domain. D domains are utilized in both conventional chimeric antigen receptors as well as our ARC-sparX platform, a next generation CAR T cell therapy, which separates antigen recognition from the T cell effector function. We describe the D domain library design, selection and screening approaches as well as the characterization and manufacture of these novel therapeutics.

10:00 Rational Selection of Building Blocks for the Assembly of Bispecific Antibodies

Fernando Garces, PhD, Principal Scientist, Therapeutic Discovery, Amgen

We describe Chain Selectivity Assessment, a high-throughput method to rationally select parental monoclonal antibodies to make bispecific antibodies requiring correct heavy/light chain pairing. With CSA, we have successfully identified mAbs that exhibit a native preference towards cognate chain pairing that enables the production of hetero-IgGs without additional engineering. CSA also identified rare light chains that permit positive binding of the non-cognate arm in the common LC hetero-IgGs, also without engineering.

10:20 CO-PRESENTATION: Experience Matters: Creative Solutions to Overcome Challenges in Antibody Drug Discovery

ABLEXIS

AlivaMab DISCOVERY SERVICES

Larry Green, Ph.D., CEO, Ablexis

John "Lippy" Lippincott, Ph.D., VP of Research, AlivaMab Discovery Services

Even with the best platforms, antibody drug discovery projects often present unique challenges. AlivaMab Discovery Services overcomes these challenges by combining Ablexis' AlivaMab® Mouse, the leading platform for successful human therapeutic antibody discovery, with innovative platform processes and deep expertise to deliver superior antibody candidates in just weeks. Watch as we present some of our approaches for delivering diverse leads that meet client requirements for challenging targets and design goals.

10:50 LIVE PANEL DISCUSSION: Discovery for Challenging Targets and Indications

Moderator: Fernando Garces, PhD, Principal Scientist, Therapeutic Discovery, Amgen

Panelists:

Stéphane Birklé, PhD, Professor, Pharmaceutical and Biological Sciences, University of Nantes, France

Naoka Hironiwa, Senior Scientist, Chugai Pharmaceutical Co., Ltd., Japan

David LaFleur, Senior Director Discovery, Research & Translational Sciences, Arcellx Inc.

Larry Green, Ph.D., CEO, Ablexis

John "Lippy" Lippincott, Ph.D., VP of Research, AlivaMab Discovery Services

11:10 Session Break - View Our Virtual Exhibit Hall

LIVE PLENARY PANEL

11:30 Live Plenary Panel: Antibody and Vaccine Development for COVID-19




Moderator: Erica Ollmann Saphire, PhD, Professor, La Jolla Institute for Immunology

- What didn't go well during the pandemic?
- What is the future? Will there be an mRNA vaccine for influenza?
- What did we learn about our country's ability to manufacture during surge production?
- What is needed in terms of infrastructure?

Panelists:

Peter Hotez, MD, PhD, FASTMH, FAAP, Dean, National School of Tropical Medicine; Professor, Departments of Pediatrics, Molecular Virology & Microbiology; Co-Head, Section of Pediatric Tropical Medicine; Health Policy Scholar, Baylor College of Medicine

Lakshmi Krishnan, PhD, A/Vice-President, Life Sciences, National Research Council Canada, Government of Canada

Peter W. Marks, MD, PhD, Director, FDA CBER

12:15 pm Session Break - View Our Virtual Exhibit Hall

BREAKOUT DISCUSSIONS

12:30 Problem Solving Discussions

Join your colleagues and fellow delegates for a focused, informal discussion moderated by a member of our speaking faculty. A small group format allows participants to meet potential collaborators, share examples from their own work and discuss ideas with peers. See website for a full list of topics.

TABLE: Can Machine Learning Accelerate Biotherapeutic Discovery?

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

1:10 Session Break - View Our Virtual Exhibit Hall

MODELING AND MACHINE LEARNING

1:20 Machine Learning to Accelerate Diagnostics and Therapeutics for COVID-19

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

I will describe machine learning methods for accelerating nanobody discovery developed together with experimental collaborators to ensure rapid design-build-test cycles. We design sequence libraries to optimize expression, stability, specificity and diversity using "alignment-free" machine learning methods, followed by learning specific binders from deep-sequencing of early rounds. In a pilot study, a 105-nanobody library showed better expression than a state-of-art, 1000-fold larger synthetic library while retaining the capacity to bind antigen.

1:40 Antibody Discovery and Development with Phage-Displayed Synthetic Antibody Libraries Designed with Computational Methods

An-Suei Yang, PhD, Professor, Physical & Computational Genomics, Genomics Research Center, Academia Sinica, Taiwan

We accomplished antibody discoveries against the nucleocapsid (N) protein of SARS-CoV-2 by working with phage-displayed synthetic antibody libraries designed with artificial intelligence models trained on antibody-antigen interactions. This work establishes a technological platform for rapidly developing lateral flow immunoassay (LFIA) devices in responding not only to the current COVID-19 pandemic but also in managing other infectious disease outbreaks in humans and animals.

IMMUNOGENICITY ASSESSMENT AND MITIGATION

2:00 Immunogenicity Risk Assessment Strategies for Engineered Antibodies

Michael D. Swanson, PhD, Senior Scientist, Biologics & Vaccines Bioanalytics, Merck & Co., Inc.

Therapeutic proteins have an inherent-sequence based immunogenicity risk. *In silico* methods are used to predict MHC class II binding epitopes derived from therapeutic proteins and estimate immunogenicity risk. Further engineering of antibodies and other therapeutic proteins can modify this risk. In this talk, I will discuss challenges, current methods, and potential solutions of how to assess the immunogenicity risk of engineered antibodies and proteins.

2:20 Preclinical Immunogenicity Assessment and De-Immunization of Antibodies

Yi Wen, PhD, Research Scientist, Lilly Research Laboratories, Eli Lilly & Co.

Biotherapeutics undergo several critical steps to elicit CD4+ T cell dependent anti-drug antibody responses. Current preclinical immunogenicity risk assessment focuses on these steps using a panel of tools and assays, including *in silico* prediction, dendritic cell internalization, MAPPS, T cell activation, and pre-existing reactivity. All data shall be considered holistically to enable molecule selection and de-immunization engineering. Herein, an integrated immunogenicity risk assessment approach was presented with case examples.

2:40 Integration of Machine Learning, Synthetic Biology and Leap-In Transposons to Better Develop Antibodies.

Claes Gustafsson, Dr, Co-Founder and CCO, ATUM

Modern Machine Learning search algorithms in conjunction with the ability to synthesize sets of systematically varied antibodies allow the search of very large space (>1015) with just a few hundred antibody variants, enabling multidimensional optimization of 'hard-to-measure' antibody functions. We integrate this engineering process directly into Leap-In transposon-mediated stable cell lines for rapid generation of gram quantities of target antibodies.

3:00 Session Break - View Our Virtual Exhibit Hall

3:10 LIVE PANEL DISCUSSION: Computational Modeling in Preclinical Development

Moderator: Michael D. Swanson, PhD, Senior Scientist, Biologics & Vaccines Bioanalytics, Merck & Co., Inc.

Panelists:

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

Yi Wen, PhD, Research Scientist, Lilly Research Laboratories, Eli Lilly & Co.

An-Suei Yang, PhD, Professor, Physical & Computational Genomics, Genomics Research Center, Academia Sinica, Taiwan

Claes Gustafsson, Dr, Co-Founder and CCO, ATUM

3:30 Close of Conference

ONCOLOGY STREAM

Advancing Antibody Therapeutics to the Clinic

The Oncology Stream at PEGS is back to share what is new in the fight against cancer, and the antibody developments that are leading the charge. Drug discovery in oncology has relied on antibodies as a tool to determine therapeutic success. Bispecific antibodies and cell engagers, as well as antibody-drug conjugates, are all utilized to improve targeted therapy and drug delivery. This year, we will look at how these impact the clinical journey from discovery to trials, whether as a single agent or in combinations. We will investigate the role of the tumor microenvironment and microbiome, and what is next on the horizon in biologic development in oncology.

2021
ONCOLOGY STREAM
CONFERENCES

May 11-12

Antibodies for Cancer Therapy

AGENDA

May 12-13

Driving Clinical Success in Antibody-Drug Conjugates

AGENDA

PEGSBOSTON
CONFERENCE STREAMS

- ENGINEERING
- ONCOLOGY
- BISPECIFIC ANTIBODIES
- IMMUNOTHERAPY
- EXPRESSION
- ANALYTICAL
- IMMUNOGENICITY
- COVID INTERVENTIONS

MAY 11-12, 2021 | 11th Annual

ANTIBODIES FOR CANCER THERAPY

Driving Breakthrough Therapies

TUESDAY, MAY 11

COMBINATORIAL APPROACHES USING RADIOTHERAPY AND IMMUNOTHERAPY

9:00 am KEYNOTE PRESENTATION: Optimal Sequencing of Radiation and Immunotherapy

Silvia C. Formenti, MD, Chairman & Professor, Radiation Oncology, Cornell University

Radiation-induced DNA damage response (DDR) is sensed by the innate immune system and can contribute to immune rejection of tumors. When successful at immunizing, radiotherapy evokes T cell memory, and induces effects outside the treated field, defined as abscopal effects (responses at a distant, synchronous, un-irradiated established tumor or metastasis).

9:20 T Cell Differentiation States in the Irradiated Tumor Microenvironment that Drive Responses to CTLA-4 Blockade

Sandra Demaria, MD, Professor of Radiation Oncology, Professor of Pathology and Laboratory Medicine, Weill Cornell Medicine

Preclinical and clinical evidence supports the ability of focal tumor radiotherapy (RT) in combination with CTLA4 blockade therapy to induce the activation and expansion of tumor-specific T-cells. I will present recent data showing that RT drives increased clonality of intratumoral CD8 T-cells, while CTLA4 blockade drives polyfunctional cytokine-producing CD4 and CD8 T-cells, and in combination they lead to the development of an effective anti-tumor immune response.

9:40 Multiple Obstacles Need to be Overcome to Prevent Resistance to CAR T Cell Therapy of Solid Tumors

Dan G. Duda, PhD, Associate Professor, Radiation Oncology, Massachusetts General Hospital

I will provide an overview of the current developments in CAR T cell therapy and highlight the unique opportunities and challenges in combining CAR T cell therapy with radiotherapy.

10:00 Accelerating High-Throughput Antibody Purification with Multi-Platform PhyTip Columns

Biotage

Shadie Nimri, BSc, Application Scientist, Biomolecules, Biotage

10:20 Humanized Immunoglobulin Models to Facilitate the Discovery of Novel Mono- or Bispecific/Multispecific Antibodies

Li Hui, Ph.D., Scientific Director, Biocytogen

The force of natural evolution determines the intrinsic complexity of our immune system that can't be surpassed by *in vitro* design. Biocytogen established immunoglobulin humanized mouse platforms: RenMab, RenLite and RenMab HiTS. These platforms have been proved to generate high-quality antibody hits that show solid developability. RenLite is a powerful tool for bispecific antibody discovery, RenMab HiTS breaks immune tolerance and shows hyper immunity against challenging targets.

10:50 LIVE PANEL DISCUSSION: Combinatorial Approaches Using Radiotherapy and Immunotherapy

Moderator: Soldano Ferrone, PhD, Professor-in-Residence, Surgery, Massachusetts General Hospital
Panelists:
Silvia C. Formenti, MD, Chairman & Professor, Radiation Oncology, Cornell University
Sandra Demaria, MD, Professor of Radiation Oncology, Professor of Pathology and Laboratory Medicine, Weill Cornell Medicine
Dan G. Duda, PhD, Associate Professor, Radiation Oncology, Massachusetts General Hospital
Li Hui, Ph.D., Scientific Director, Biocytogen
Shadie Nimri, BSc, Application Scientist, Biomolecules, Biotage

11:10 Session Break - View Our Virtual Exhibit Hall

11:10 ASK THE EXPERT with Svar Life Science

SVAR

Michael G. Tovey, Ph.D, Chief Scientific Advisor of Svar Life Science France, Svar Life Science

Svar´s Expert session will focus on AAV mediated gene therapy and potential neutralizing antibody response to AAV vectors. We know the importance of precisely quantify both the neutralizing antibody response prior to treatment, and the neutralizing antibody response to the recombinant AAV vector following treatment. Talk to us about how our highly sensitive reporter-gene assays are used for the quantification of NAbs to recombinant AAV vectors with different capsid specificities.

PLENARY KEYNOTE ADDRESS

11:25 Plenary Keynote Introduction

Jennifer R. Cochran, PhD, Shriram Chair & Professor, Bioengineering & Chemical Engineering, Stanford University

11:30 KEYNOTE PRESENTATION: The Coming of Age of *de Novo* Protein Design

David A. Baker, PhD, Henrietta & Aubrey David Endowed Professor, Biochemistry, University of Washington

I will describe the *de novo* design of fluorescent proteins, membrane penetrating macrocycles, transmembrane protein channels, allosteric proteins that carry out logic operations, and self-assembling nanomaterials and polyhedra. I will also discuss the application of these methods to COVID-19 challenges.

12:00 pm LIVE: Q&A with Audience

Moderator: Jennifer R. Cochran, PhD, Shriram Chair & Professor, Bioengineering & Chemical Engineering, Stanford University
Panelists:
David A. Baker, PhD, Henrietta & Aubrey David Endowed Professor, Biochemistry, University of Washington

12:10 Session Break - View Our Virtual Exhibit Hall

BREAKOUT DISCUSSIONS

12:20 Problem Solving Discussions

Join your colleagues and fellow delegates for a focused, informal discussion moderated by a member of our speaking faculty. A small group format allows participants to meet potential collaborators, share examples from their own work and discuss ideas with peers. See website for a full list of topics.

CO-PRESENTATION: TABLE: Barriers in the Tumor Microenvironment

Soldano Ferrone, PhD, Professor-in-Residence, Surgery, Massachusetts General Hospital
Dan G. Duda, PhD, Associate Professor, Radiation Oncology, Massachusetts General Hospital

- Vascular barrier in tumors
- Multiple roles of hypoxia (low oxygen) in tumor tissue
- The role of extracellular matrix
- The role of myeloid cells in the tumor microenvironment

*** Presentations delivered via a live, interactive video conferencing platform. ***

TABLE OF CONTENTS

1:00 Session Break - View Our Virtual Exhibit Hall

BIOINFORMATICS FOR TARGET DISCOVERY AND VALIDATION

1:10 Interpreting Genomic Alterations and Therapeutic Implications Using OncoKB and the cBioPortal for Cancer Genomics

Nikolaus Schultz, PhD, Associate Attending Computational Oncologist, Epidemiology & Biostatistics, Memorial Sloan Kettering Cancer Center

With prospective clinical sequencing of tumors emerging as a mainstay in cancer care, an urgent need exists for clinical support tools that identify the clinical implications associated with specific mutation events. To this end, we have developed two complementary tools for the interpretation and visualization of cancer variants, enabling researchers and clinicians to make discoveries and treatment decisions.

1:30 Open Targets: Integration of Evidence for Drug Target Identification and Prioritisation

Ian Dunham, PhD, Scientific Director, Open Targets, EMBL EBI Hinxton

Embarking on a new drug discovery project is fraught with risk. The correct choice of target and therapeutic hypothesis is key to success. I will describe how the Open Targets program integrates data generation and bioinformatics to provide an integrated target identification and prioritisation platform.

1:50 The Expanding Repertoire of Actionable Alterations in the Fibroblast Growth Factor Receptors

Ian M. Silverman, PhD, Principal Investigator, Translational Sciences, Incyte Corp.

Activating genomic alterations in the fibroblast growth factor receptor (*FGFR*) gene family occur in many tumor types, and include a multitude of distinct mutations and fusions. We queried *FGFR* genomic alterations in a large database of patient tumor samples analyzed using comprehensive genomic profiling. Our study reveals new insights into the landscape of *FGFR* genomic alterations across tumor types and identified a novel class of alterations with potential actionability.

2:10 Talk Title to be Announced

Speaker to be Announced, GenScript

2:40 LIVE PANEL DISCUSSION: Bioinformatics for Target Discovery and Validation

Moderator: Horacio G. Nastri, PhD, Executive Director, Antibody Discovery, Incyte Corporation
Panelists:
Nikolaus Schultz, PhD, Associate Attending Computational Oncologist, Epidemiology & Biostatistics, Memorial Sloan Kettering Cancer Center
Ian Dunham, PhD, Scientific Director, Open Targets, EMBL EBI Hinxton
Ian M. Silverman, PhD, Principal Investigator, Translational Sciences, Incyte Corp.
Speaker to be Announced, GenScript

3:00 PEGS Connects - View Our Virtual Exhibit Hall

BIOENGINEERED ANTIBODIES FOR RECYCLED TARGETS

3:10 Bioengineering of Bispecific Antibodies – New Developments and Relevance of Binder-Format Combinations

Ulrich Brinkmann, PhD, Expert Scientist, Pharma Research & Early Development, Roche Innovation Center Zurich

The presentation covers recent advances of our engineering and applications of bispecific antibodies and engineered derivatives. New data and examples are presented that demonstrate the importance of combining suitable binders and formats to produce bsAbs with desired functionalities. We also demonstrate that large binder-format matrices can be covered by our novel FORCE technology.

3:30 Development of Recombinant Immunotoxins for Adult Leukemias

Robert J. Kreitman, MD, Chief Clinical Immunotherapy, Lab of Molecular Biology, NIH NCI

Recombinant immunotoxin BL22 targeting CD22 achieved CRs as a single agent in chemoresistant HCL and an improved version Moxetumomab Pasudotox (Moxe) was FDA approved for relapsed/refractory HCL. Current efforts to improve the activity of Moxe in HCL include combination with anti-CD20 Mab to prevent immunogenicity and improve cytotoxicity.

3:50 Anti-Folate Receptor Alpha C'Dot Drug Conjugates (CDCs) for the Treatment of Cancer

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

Elucida is developing ultra-small tumor-targeted nanoparticle drug conjugates for the treatment of cancer. CDCs' unique properties, including their 6-7 nm size, silica core and PEG layer allow them to rapidly target and penetrate into tumors with minimal normal tissue retention – attractive qualities for payload delivery vehicles. Preclinical studies with Elucida's lead anti-folate receptor alpha CDC EC112002 will be presented.

4:20 LIVE PANEL DISCUSSION: Bioengineered Antibodies for Recycled Targets

Moderator: Daniel A. Vallera, PhD, Lion Scholar and Professor; Director, Section on Molecular Cancer Therapeutics; Professor, Therapeutic Radiology, University of Minnesota Masonic Cancer Center
Panelists:
Ulrich Brinkmann, PhD, Expert Scientist, Pharma Research & Early Development, Roche Innovation Center Zurich
Robert J. Kreitman, MD, Chief Clinical Immunotherapy, Lab of Molecular Biology, NIH NCI
Gregory P. Adams, PhD, CSO, Elucida Oncology, Inc.
Arthur E. Frankel, MD, Chief, Hematology/Oncology, University of South Alabama

4:40 Close of Day One

3:30 SC1: CAR T Cell Therapy from A-Z SC2: Introduction to Gene Therapy Products Manufacturing and Analytics

Separate registration required. See short course page for details.

WEDNESDAY, MAY 12

GLYPICANS AS A NEW FAMILY OF TARGETS

9:00 am GPC3-CAR T Cells for the Treatment of Solid Tumors

Andras A. Heczey, MD, Assistant Professor & Director, Pediatrics & Oncology, Texas Children's Hospital

Targeting GPC3 with T cells expressing chimeric antigen receptors has the potential to cure patients with solid cancers expressing this antigen. The presentation will discuss the development of GPC3-CARs and the effect of IL15 and IL21 co-expression in GPC3-CAR T cells examined in preclinical models and show the emerging results of two clinical trials enrolling patients.

9:20 ERY974, an Anti-Glypican 3/CD3 Bispecific T Cell-Redirecting Antibody for Treatment of Solid Tumors

Junichi Nezu, PhD, Vice President & Head, Research Division, Chugai Pharmaceutical Co. Ltd.

We developed a bispecific antibody, ERY974; it targets glypican 3 (GPC3) whose expression is highly specific to many types of solid tumors, such as hepatoma and non-small cell lung carcinoma. ERY974 exerts strong anti-tumor activity against a variety of tumor models including those with a non-inflamed phenotype. In this talk, I will discuss the detailed preclinical characterization of ERY974, including the cytokine release mechanism and potential combination therapies.

9:40 Development of GPC2-Targeted CAR T Cells for Treating Childhood Cancer

Nan Li, PhD, Staff Scientist, Molecular Biology Lab, NIH NCI

Glypican 2 (GPC2) is a cell surface proteoglycan overexpressed in childhood cancer. We discover a high affinity monoclonal antibody, CT3, that specifically recognizes GPC2. CT3-derived CAR T cells regress tumors in advanced neuroblastoma mouse models, providing a strategy to improve current therapies for treating childhood cancer.

10:00 Single B Cell SMab™ Platform and its Applications in Monoclonal Antibody Discovery

Hai Wu, Ph.D., Chief Technology Officer, Antibody Division, ABclonal Technology

ABclonal has developed a novel monoclonal antibody (mAb) discovery platform, SMab™ platform, based on single B cell isolation, culture, and cloning. Using universal SMab™ platform, ABclonal can rapidly develop monoclonal antibodies from a panel of hosts including rabbit, llama, and human. This has significantly shortened the mAb screening process with greater diversity and efficiency, and allows ABclonal to deliver the best-in-class rabbit monoclonal antibodies (RmAb) to our CRO clients.

10:20 Expand and improve your antibody candidate pool by integrating high-throughput sequencing

Piotr van Rijssel, Application Specialist, ENPICOM

The integration of high-throughput sequencing data in antibody screening accelerates and improves discovery of novel therapeutic antibodies. Discover how you can perform efficient, integrated analysis to improve and expand your antibody candidate pool with NGS data.

10:50 LIVE PANEL DISCUSSION: Glypicans as a New Family of Targets

Moderator: Mitchell Ho, PhD, Senior Investigator; Deputy Chief, Laboratory of Molecular Biology; Director, Antibody Engineering Program, National Cancer Institute (NCI), NIH
Panelists:
Andras A. Heczey, MD, Assistant Professor & Director, Pediatrics & Oncology, Texas Children's Hospital
Junichi Nezu, PhD, Vice President & Head, Research Division, Chugai Pharmaceutical Co. Ltd.
Nan Li, PhD, Staff Scientist, Molecular Biology Lab, NIH NCI
Hai Wu, Ph.D., Chief Technology Officer, Antibody Division, ABclonal Technology
Piotr van Rijssel, Application Specialist, ENPICOM

11:10 Session Break - View Our Virtual Exhibit Hall

11:10 CO-PRESENTATION: ASK THE EXPERT with SCIEX

Matt Stone, Biologics Workflow Specialist, SCIEX
Mukesh Malik, Sr. Application Scientist, SCIEX

Join SCIEX analytical technology experts Matthew Stone and Mukesh Malik during an interactive Q&A session to discuss analytical development and optimization of capillary electrophoresis and liquid chromatography-mass spectrometry based methods for protein characterization and quantification. Exciting topics covered include mAbs and mAb variants, cell and gene therapy, vaccines and more!

YOUNG SCIENTIST KEYNOTE

11:25 Young Scientist Keynote Introduction

Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute

11:30 KEYNOTE PRESENTATION: Cryo-Electron Microscopy Structures of Spike Glycoproteins Suggest Pan-Coronavirus Antiviral Strategy

Christine Toelzer, Research Associate, University of Bristol, United Kingdom

We research antivirals to combat present and future coronavirus pandemics. We discovered linoleic acid bound to a hydrophobic pocket in the Cryo-EM structure of the SARS-CoV-2 Spike glycoprotein. Ligand binding locked the protein in a compact closed conformation. Conservation of key AA residues suggested a similar pocket exists in other pathogenic coronaviruses.

12:00 pm Live: Q&A with Young Scientist Keynote

Moderator: Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute
Panelists:
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

12:10 Session Break - View Our Virtual Exhibit Hall

1:00 Close of Antibodies for Cancer Therapy Conference

3:30 SC3: Developability of Bispecific Antibodies: Formats and Applications

Separate registration required. See short course page for details.

DRIVING CLINICAL SUCCESS IN ANTIBODY-DRUG CONJUGATES

Lessons Learned and New Engineering Approaches for Next Wave ADCs

WEDNESDAY, MAY 12

YOUNG SCIENTIST KEYNOTE

11:25 am Young Scientist Keynote Introduction
Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute

11:30 KEYNOTE PRESENTATION: Cryo-Electron Microscopy Structures of Spike Glycoproteins Suggest Pan-Coronavirus Antiviral Strategy
Christine Toelzer, Research Associate, University of Bristol, United Kingdom
We research antivirals to combat present and future coronavirus pandemics. We discovered linoleic acid bound to a hydrophobic pocket in the Cryo-EM structure of the SARS-CoV-2 Spike glycoprotein. Ligand binding locked the protein in a compact closed conformation. Conservation of key AA residues suggested a similar pocket exists in other pathogenic coronaviruses.

12:00 pm Live: Q&A with Young Scientist Keynote
Moderator: Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute
Panelists:
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

12:10 Session Break - View Our Virtual Exhibit Hall

CLINICAL AND PRECLINICAL LESSONS LEARNED

1:10 KEYNOTE PRESENTATION: PADCEV (enfortumab vedotin): Road from Development to Approval
Marjorie C. Green, PhD, Senior Vice President & Head, Late Stage Development, Seagen
This talk will discuss the journey of PADCEV from IND through US accelerated approval and beyond. ADCs are a new therapeutic class in bladder cancer and this talk will discuss PADCEV's unique mechanism of action as well as the efficacy/safety of PADCEV in metastatic urothelial cancer. In addition, the talk will discuss ongoing exploration of its activity in early bladder cancer and other disease types.

1:30 NBE-002, an Anthracycline-Based Immune-Stimulatory Antibody-Drug Conjugates (iADC) Targeting ROR1 for the Treatment of Solid Tumors
Roger Beerli, PhD, CSO, NBE-Therapeutics Ltd.
We present preclinical data on NBE-002, a novel ROR1-targeting ADC based on Sortase A-mediated, site-specific conjugation of a derivative of the highly potent anthracycline PNU-159682. NBE-002 is an effective and promising targeted therapeutic for the treatment of ROR1-positive TNBC and other solid tumor indications and is currently in clinical development. Due to immune-modulatory functions of the PNU payload, NBE-002 is particularly well suited for combination therapy with immune checkpoint inhibitors.

1:50 Antibody-Targeted Amanitin Conjugates (ATACs) Overcome Resistance Mechanisms and Provide New Treatment Options for Difficult to Treat Cancers
Torsten Hechler, PhD, Vice President, ADC Research, Cell Biology & Biochemistry, Heidelberg Pharma Research GmbH
Antibody-Targeted Amanitin-Conjugates (ATACs) introduce a new mode of action into oncology therapy. The inhibition of RNA polymerase II facilitates killing of dormant tumor cells (CSCs, TICs) and offers new treatment options for difficult to treat cancers and high-risk patients. The unique MOA with a demonstrated safety profile might pave the way for accelerated development and approval. HDP-101 is a BCMA-ATAC entering Phase I trials for Multiple Myeloma in 2021.

2:10 Targeting Folate Receptor Alpha (FRα) with IMGN151, a Next-Generation Antibody-Drug Conjugate
Olga Ab, PhD, Associate Director, Translational Sciences, ImmunoGen Inc.
Mirvetuximab soravtansine, our first-generation FRa-targeting ADC is in two phase III studies, MIRASOL and SORAYA, in patients with platinum-resistant epithelial ovarian cancer with high levels of FRa. To address the unmet need of additional patient populations, we developed a next-generation anti-FRa ADC, IMGN151, which is active against tumors with a broader range of FRa expression. IMGN151's innovative design, including the biparatopic antibody, and favorable preclinical activity will be presented.

2:30 Catalent's SMARTag® Technology: Differentiated Solutions for Optimal ADCs
Stepan Chuprakov, Chemistry Group Leader, Catalent, Science and Development, Catalent Biologics
SMARTag is a clinical-stage ADC technology featuring site-specific conjugation with multiple linker and warhead options. TRPH-222, a CD22-targeted SMARTag conjugate in the dose-escalation stage of a Phase 1 trial for R/R B-cell lymphoma, has achieved 6 CRs and 2 PRs among 22 patients to date. In addition to site-specific conjugation, we have developed new linkers to achieve proprietary high DAR ADCs featuring topoisomerase I inhibitor payloads.

3:00 LIVE PANEL DISCUSSION: Lessons Learned from Past Successes and Failures
Moderator: John M. Lambert, PhD, Consultant
Panelists:
Olga Ab, PhD, Associate Director, Translational Sciences, ImmunoGen Inc.
Roger Beerli, PhD, CSO, NBE-Therapeutics Ltd.
Stepan Chuprakov, Chemistry Group Leader, Catalent, Science and Development, Catalent Biologics
Marjorie C. Green, PhD, Senior Vice President & Head, Late Stage Development, Seagen
Torsten Hechler, PhD, Vice President, ADC Research, Cell Biology & Biochemistry, Heidelberg Pharma Research GmbH

3:20 PEGS Connects - View Our Virtual Exhibit Hall

3:30 SC3: Developability of Bispecific Antibodies: Formats and Applications
Separate registration required. See short course page for details.

4:00 Close of Day

THURSDAY, MAY 13

ADCS TARGETING THE IMMUNE SYSTEM

9:00 am Development of ADCs Targeting Immune Cells to Overcome TGF-ß-Induced Tumor Suppression
Dori Thomas-Karyat, PhD, Founder & CEO, Synthis Therapeutics
TGF-b is one of the most immuno-suppressive cytokines in virtually all solid tumors. Despite long-standing interesting in TGF-b therapies for cancer patients, systemic TGF-b have had limited success, since they cause severe toxicity, particularly in the heart. Synthis is an early stage biotech company, developing a first in class, cell-targeted therapeutic platform that selectively reverses TGF-b mediated immune suppression to safely drive tumor clearance.

9:20 Stromal Targeting Antibody-Drug Conjugates – Learnings from ABBV-085
James W. Purcell, PhD, Project Director, Oncology Discovery, AbbVie Inc.
This talk will summarize learnings from stromal targeting antibody-drug conjugates both preclinically and clinically. Findings from ABBV-085 which targets the stromal antigen LRRC15 which is highly expressed on cancer associated fibroblasts (CAFs) in the tumor microenvironment, will be discussed. Preclinical and Phase 1 findings will be summarized, with a view to highlighting challenges and opportunities for targeting stromal antigens with antibody-drug conjugates.

9:40 TM4SF1, an Attractive Vascular and Tumor Cell Target for Antibody-Drug Conjugate Therapy

Shou-Ching Jaminet, PhD, Founder & Head of Research, Pathology, Angiex Inc.

Nuclear-Delivered Antibody-Drug Conjugates™ (ND-ADCs) are a novel form of ADC which benefit from direct internalization of the ADC to the nucleus. Angiex has developed the first ND-ADC for solid tumors, AGX101, which will enter the clinic in late 2021. AGX101 has two mechanisms of action due to its expression in both tumor cells and angiogenic endothelial cells. AGX101 has demonstrated excellent efficacy and safety in preclinical animal models.

10:00 XMT-2056, a Well-Tolerated, Immunosynthen-based STING Agonist Antibody-Drug Conjugate Elicits Potent Anti-Tumor Immune Responses with Minimal Induction of Systemic Cytokines

Raghida A. Bukhalid, PhD, Director, Oncology Drug Discovery & Development, Mersana Therapeutics

We designed Immunosynthen, a novel STING agonist antibody-drug conjugate platform ideally suited for systemic administration of STING agonists with reduced toxicity. XMT-2056, an Immunosynthen-based tumor antigen-targeted STING agonist ADC exhibits excellent drug-like properties and >100-fold increased potency as compared to the free STING agonist. XMT-2056 is well-tolerated in non-human primates, and the ADC exhibits favorable pharmacokinetics after repeat doses. Together these data support the clinical development of XMT-2056.

10:20 Sponsored Presentation *(Opportunity Available)*

10:50 LIVE PANEL DISCUSSION: ADCs Modulating the Tumor Microenvironment

Moderator: Greg M. Thurber, PhD, Associate Professor, Chemical Engineering & Biomedical Engineering, University of Michigan
Panelists:
Raghida A. Bukhalid, PhD, Director, Oncology Drug Discovery & Development, Mersana Therapeutics
Shou-Ching Jaminet, PhD, Founder & Head of Research, Pathology, Angiex Inc.
James W. Purcell, PhD, Project Director, Oncology Discovery, AbbVie Inc.
Dori Thomas-Karyat, PhD, Founder & CEO, Synthis Therapeutics

11:10 Session Break - View Our Virtual Exhibit Hall

LIVE PLENARY PANEL

11:30 Live Plenary Panel: Antibody and Vaccine Development for COVID-19




Moderator: Erica Ollmann Saphire, PhD, Professor, La Jolla Institute for Immunology

- What didn't go well during the pandemic?
- What is the future? Will there be an mRNA vaccine for influenza?
- What did we learn about our country's ability to manufacture during surge production?
- What is needed in terms of infrastructure?

Panelists:
Peter Hotez, MD, PhD, FASTMH, FAAP, Dean, National School of Tropical Medicine; Professor, Departments of Pediatrics, Molecular Virology & Microbiology; Co-Head, Section of Pediatric Tropical Medicine; Health Policy Scholar, Baylor College of Medicine
Lakshmi Krishnan, PhD, A/Vice-President, Life Sciences, National Research Council Canada, Government of Canada
Peter W. Marks, MD, PhD, Director, FDA CBER

12:15 pm Session Break - View Our Virtual Exhibit Hall

12:30 Problem Solving Discussions

Join your colleagues and fellow delegates for a focused, informal discussion moderated by a member of our speaking faculty. A small group format allows participants to meet potential collaborators, share examples from their own work and discuss ideas with peers. See website for a full list of topics.

BREAKOUT DISCUSSIONS

TABLE: Linker Matters – Novel Linker Technologies and Its Impact on ADC Success

Philipp Spycher, PhD, CEO, Araris Biotech AG

During this roundtable session the following points will be discussed:

- Role of linker in ADC design and its key properties
- Cleavable and non-cleavable linkers
- Novel linker technologies

1:10 Session Break - View Our Virtual Exhibit Hall

ENGINEERING, DELIVERY & DOSING STRATEGIES

1:20 Increasing the Performance of ADCs with KSP-Inhibitor Payloads via a Tailored Design of Linker and Metabolite Profile

Hans-Georg Lerchen, PhD, CSO, Vincerx Pharma Inc.

We envisioned a preferential activation of ADCs in tumor versus healthy tissues to improve the therapeutic window. Towards this goal we developed ADCs with novel linkers which are efficiently and selectively cleaved by the tumor-associated protease legumain. A remarkable tolerability of legumain for different linker peptides together with a modifier of the physicochemical catabolite profile allow for a tailored design of ADCs for different targets.

1:40 Small Molecule-Drug Conjugates: Getting Small to Enhance Targeting

Samuele Cazzamalli, PhD, Group Head - Senior Scientist, Philochem AG

Clinical efficacy of ADC products is hindered by their slow and inefficient accumulation in solid tumors. Small molecule-drug conjugates (SMDCs) have been recently proposed as an alternative approach to effectively deliver potent cytotoxic compounds to the neoplastic site and to solid metastatic lesions. We are developing SMDC products to target potent anti-tubulin poisons to solid tumors expressing CAIX and FAP.

2:00 Engineering a HER2-Specific Antibody-Drug Conjugate to Increase Lysosomal Delivery and Therapeutic Efficacy at Lower Doses

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

Despite major advances in antibody-drug conjugate (ADC) technology, dose-limiting toxicities that limit therapeutic efficacy are frequently observed. We have engineered the antibody component of a HER2-specific ADC to result in more efficient lysosomal delivery following internalization into cells. The engineered ADC (ALTA, for ADC with increased lysosomal trafficking activity) is expected to lead to reduced off-tumor toxicities by enabling the use of lower doses.

2:20 Alternatives to ValCitPABC: New Cleavable Linker and Self-Immolation Strategies ADCs

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

There continues to be a need for new ADC linker strategies for the lysosomal release of payloads. We have undertaken an effort to prepare and screen a peptide library for new cleavable linkers. We will describe new legumain-cleavable linkers that we have identified from this work – and will also report preliminary work for the optimization of new self-immolative spacers for the release of alcohols and anilines.

2:40 Sponsored Presentation *(Opportunity Available)*

3:10 LIVE PANEL DISCUSSION: Engineering, Delivery and Dosing Strategies for Next-Gen ADCs

Moderator: Robert J Lutz, PhD, Principal Consultant, Crescendo Biopharma Consulting
Panelists:
Samuele Cazzamalli, PhD, Group Head - Senior Scientist, Philochem AG
Hans-Georg Lerchen, PhD, CSO, Vincerx Pharma Inc.
Nathan L. Tumey, PhD, Assistant Professor, Pharmaceutical Sciences, SUNY Binghamton
E. Sally Ward, PhD, Director, Translational Immunology; Professor, Molecular Immunology, Centre for Cancer Immunology, University of Southampton

3:30 Close of Conference

BISPECIFIC ANTIBODIES STREAM

Driving Innovation in Biologics

Bispecific antibodies are at the center of a vibrant area in antibody engineering with a growing range of platforms that has led to numerous constructs with novel functionality. The Bispecifics stream at PEGS will showcase the latest developments in novel platforms and engineering to optimize clinical performance and minimize adverse effects. Join the two foremost events of the year to gain a comprehensive view of bispecific antibodies, network with leaders in the industry and hear about the latest clinical results.

2021 BISPECIFIC ANTIBODIES STREAM CONFERENCES

May 11-12

Advancing Bispecific Antibodies and Combination Therapy to the Clinic

AGENDA

May 12-13

Engineering Bispecific Antibodies

AGENDA

PEGSBOSTON CONFERENCE STREAMS

- ENGINEERING
- ONCOLOGY
- **BISPECIFIC ANTIBODIES**
- IMMUNOTHERAPY
- EXPRESSION
- ANALYTICAL
- IMMUNOGENICITY
- COVID INTERVENTIONS

MAY 11-12, 2021 | 7th Annual

ADVANCING BISPECIFIC ANTIBODIES AND COMBINATION THERAPY TO THE CLINIC

Creating the Killer Combo

TUESDAY, MAY 11

ADVANCING CO-STIMULATORY BISPECIFIC ANTIBODIES

9:00 am Tumor-Targeted CD28 Costimulatory Bispecific Antibodies Enhance T Cell Activation in Solid Tumors

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

Solid tumors often lack expression of CD28 ligands, so we hypothesized that activation of CD28 signaling in the tumor micro-environment could be beneficial. We designed B7H3 x CD28 and PDL1 x CD28 bispecific antibodies that conditionally costimulate CD28 only in the presence of their respective targets and TCR engagement, and show that they enhance activity of either anti-PD1 antibodies or TAA x CD3 T cell engagers.

9:20 Engineering, Safety and Efficacy of Subcutaneous Izokibep, a High-Affinity Dual Binding IL-17A Inhibiting Affibody Ligand Trap, Dosed in Psoriasis Patients More than Two Years

Fredrik Frejd, PhD, CSO, Affibody AB

Multiple inflammatory disorders involves dimeric IL-17. To exclusively block the homodimeric version only, we used a small protein domain to engineer an Affibody based ligand trap that sequester IL-17 A/A with femtomolar affinity. The novel construct has demonstrated safety and efficacy more than two years in patients with plaque psoriasis.

9:40 Update on T Cell Bispecific Antibodies and Their Combination with 4-1BB Costimulation

Christian Klein, PhD, Cancer Immunotherapy Discovery, Roche Innovation Center Zurich, Roche Pharma Research & Early Development, pRED

Novel TCBs and next generation TCB approaches and an update on 4-1BB co-stimulation to boost TCB activity will be discussed.

10:00 Combinatorial Approaches to Enhance Bispecific Anti-Tumor Efficacy

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

This presentation will describe key pre-clinical data from Regeneron's clinical stage T cell redirecting bispecific programs (REGN1979, REGN4018, REGN5458) as well as status updates from the ongoing clinical trials. In addition, data from new combinatorial approaches being taken to enhance bispecific anti-tumor efficacy, focusing on costimulatory bispecifics, will be discussed.

10:20 Multispecific Antibodies – Design and Development of Next-Generation Cancer Therapeutics

Stefan Warmuth, PhD, Vice President, Head CMC, Numab Therapeutics AG

NM21-1480 is a multispecific antibody fragment-based cancer therapeutic in phase 1 clinical testing, that potently stimulates anti-cancer immune responses through concomitant induction of 4-1BB-signaling and PD-L1 blockade in the tumor microenvironment. Careful selection of format, epitopes and affinities resulted in optimized activity and a favorable safety profile in non-human primates. Additional therapeutic approaches based on Numab's MATCH™ platform are presented.

10:40 Applied BioMath Assess™ - An Early Feasibility Assessment Tool for Biotherapeutics

John Burke, PhD, Co-Founder, President and CEO, Applied BioMath

Early R&D poses many questions and challenges when determining if a biotherapeutic enters the portfolio. In this presentation we will demonstrate how our new and interactive software tool, systematically investigates the therapeutic characteristics (e.g., format, half-life, affinity, mechanism of action) given target characteristics (e.g., target expression and turnover) necessary to achieve success criteria given the predetermined target profile (e.g., dose, administration, frequency) to help accelerate and de-risk your project.

11:10 LIVE PANEL DISCUSSION: Advancing Co-Stimulatory Bispecific Antibodies

Moderator: Eric Smith, PhD, Senior Director, Bispecifics, Regeneron Pharmaceuticals, Inc.
Panelists:
Gregory L. Moore, PhD, Director, Protein Engineering, Xencor, Inc.
Fredrik Frejd, PhD, CSO, Affibody AB
Christian Klein, PhD, Cancer Immunotherapy Discovery, Roche Innovation Center Zurich, Roche Pharma Research & Early Development, pRED
Stefan Warmuth, PhD, Vice President, Head CMC, Numab Therapeutics AG
John Burke, PhD, Co-Founder, President and CEO, Applied BioMath

11:10 ASK THE EXPERT with Svar Life Science

Michael G. Tovey, Ph.D, Chief Scientific Advisor of Svar Life Science France, Svar Life Science

Svar´s Expert session will focus on AAV mediated gene therapy and potential neutralizing antibody response to AAV vectors. We know the importance of precisely quantify both the neutralizing antibody response prior to treatment, and the neutralizing antibody response to the recombinant AAV vector following treatment. Talk to us about how our highly sensitive reporter-gene assays are used for the quantification of NAbs to recombinant AAV vectors with different capsid specificities.

11:20 Session Break - View Our Virtual Exhibit Hall

PLENARY KEYNOTE ADDRESS

11:25 Plenary Keynote Introduction

Jennifer R. Cochran, PhD, Shriram Chair & Professor, Bioengineering & Chemical Engineering, Stanford University

11:30 KEYNOTE PRESENTATION: The Coming of Age of *de Novo* Protein Design

David A. Baker, PhD, Henrietta & Aubrey David Endowed Professor, Biochemistry, University of Washington

I will describe the *de novo* design of fluorescent proteins, membrane penetrating macrocycles, transmembrane protein channels, allosteric proteins that carry out logic operations, and self-assembling nanomaterials and polyhedra. I will also discuss the application of these methods to COVID-19 challenges.

12:00 pm LIVE: Q&A with Audience

Moderator: Jennifer R. Cochran, PhD, Shriram Chair & Professor, Bioengineering & Chemical Engineering, Stanford University
Panelists:
David A. Baker, PhD, Henrietta & Aubrey David Endowed Professor, Biochemistry, University of Washington

12:10 Session Break - View Our Virtual Exhibit Hall

BREAKOUT DISCUSSIONS

12:20 Problem Solving Discussions

Join your colleagues and fellow delegates for a focused, informal discussion moderated by a member of our speaking faculty. A small group format allows participants to meet potential collaborators, share examples from their own work and discuss ideas with peers. See website for a full list of topics.

TABLE: Tumor-Targeted Costimulatory Bispecific Antibodies to Enhance T Cell Activation in Solid Tumors

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

- What is the preferred choice of costimulatory receptor? CD28, 4-1BB, or other? How does this influence bispecific format?
- Which T cell populations are best to target? What about other effector cells (e.g., NK)?
- What types of *in vivo* studies are most valuable? Mouse xenograft or syngeneic tumor models, or cynomolgus monkey?
- Which clinical combinations should be pursued – CD3 bispecifics, checkpoint inhibitors, or other?

1:00 Session Break - View Our Virtual Exhibit Hall

NOT YOUR AVERAGE BISPECIFIC ANTIBODY: INNOVATIVE FORMATS AND TRIGGERED AND BISPECIFICS

1:10 KEYNOTE PRESENTATION: T Cell Engaging Antibody Circuits
Mark Cobbold, PhD, Vice President, Oncology Early Discovery, AstraZeneca Pharmaceuticals

1:30 The Next Generation of T Cell Redirecting Antibodies
Werner Meier, CSO, Revitope Oncology
Harnessing the immune system has revolutionized cancer treatment, but toxicities limit their potential. Revitope develops T cell engagers (GATEs) designed to elicit an immune response focused entirely on the tumor. The split anti-CD3 paratope requires two antigens on the same cancer cell for activity and may enable greater tumor-specificity. Protein engineering, *in vitro* and *in vivo* activity measurements and emerging mechanistic understanding of the GATE technology is covered.

1:50 XTENylated Protease-Activated T Cell Engagers (XPATs): A Novel Masked Format that Expands the Therapeutic Index for T Cell Engagers in Solid Tumors
Volker Schellenberger, PhD, President & CEO, Amunix
XPATs are masked TCEs that are preferentially unmasked to an active form in the tumor microenvironment by tumor-associated proteases. In mouse efficacy studies, masked XPATs targeting HER2 or other tumor antigens demonstrate efficacy similar to the unmasked, activated forms, while in cyno toxicity studies, the tolerated exposures (Cmax) achieved with masked XPATs are up to 500X higher than those achieved with the unmasked, activated forms.

2:10 Designed Protein Logic to Target Cells with Precise Combinations of Surface Antigens
Marc J. Lajoie, PhD, CEO, Outpace Bio
Designed protein switches perform computations on the surface of cells, enabling specific targeting of tumor cells that express precise combinations of surface antigens. Proximity-dependent activation causes a conformational change only when all conditions are met on each individual target cell, allowing targeting in mixed populations even when off-target cells share common target antigens. The talk will cover design principles and *in vitro* data.

2:30 Activating the Immune System with T Cell Engagers and Cytokine Receptor Agonists for the Treatment of Solid Tumors
Nathan D. Trinklein, PhD, CTO, TeneoBio, Inc.
Tumor-targeted immune agonist antibodies increase the therapeutic index of cancer therapies. Using NGS-based discovery, we have created a large collection of human antibodies targeting a variety of tumor antigens and activating receptors on immune cells. Our lead program, TNB-383B (BCMAxCD3) is currently in clinical development for the treatment of multiple myeloma. In addition to CD3 T cell engaging bispecific antibodies, additional immune-stimulatory multi-specific antibodies developed at Teneobio will be discussed.

2:50 Leave No Hit Behind: Accelerating Lead Molecule Discovery Against Difficult Targets
Anupam Singhal, PhD, Sr. Product Manager, Antibody Discovery, Marketing, Berkeley Lights, Inc.
In the new era of complex modalities and COVID-19 pandemic, speed, capacity, Traditional hybridoma and phage display methods have failed to yield therapeutic antibodies against difficult targets like most GPCRs and ion channels. This presentation will introduce Berkeley Lights' new Opto™ Plasma B Discovery 4.0 workflow that enables recovery of 1000s of hits by screening up to 100,000 plasma B cells, down-selection of lead candidates by functional screening, and sequencing and re-expression of >1000 functionally-characterized antibodies … all in just 1 week. By maximizing the diversity of antibodies through direct functional profiling of plasma B cells, the Opto Plasma B Discovery 4.0 workflow will allow users to tackle even the most challenging targets.

3:20 LIVE PANEL DISCUSSION: Not Your Average Bispecific Antibody: Innovative Formats and Triggered Bispecifics
Moderator: Frank Comer, PhD, Associate Principal Scientist, AstraZeneca
Panelists:
Mark Cobbold, PhD, Vice President, Oncology Early Discovery, AstraZeneca Pharmaceuticals
Werner Meier, CSO, Revitope Oncology
Volker Schellenberger, PhD, President & CEO, Amunix
Marc J. Lajoie, PhD, CEO, Outpace Bio
Nathan D. Trinklein, PhD, CTO, TeneoBio, Inc.
Anupam Singhal, PhD, Sr. Product Manager, Antibody Discovery, Marketing, Berkeley Lights, Inc.

3:40 PEGS Connects - View Our Virtual Exhibit Hall

4:00 Close of Day One

3:30 SC1: CAR T Cell Therapy from A-Z SC2: Introduction to Gene Therapy Products Manufacturing and Analytics
Separate registration required. See short course page for details.

WEDNESDAY, MAY 12

NOT YOUR AVERAGE BISPECIFIC ANTIBODY: INNOVATIVE FORMATS AND TRIGGERED BISPECIFICS

9:00 am Oncolytic Vaccines to Improve BiTE Delivery and Efficacy
Christine E. Engeland, MD, PhD, Researcher Medical & Translational Oncology, Tumor Diseases Center, German Cancer Research Center, DKFZ
Oncolytic viruses selectively infect and replicate in malignant cells, ultimately leading to tumor cell lysis and tumor vaccination effects. Due to their oncotropism, oncolytic viral vaccines can serve as vectors for tumor-targeted delivery of immunomodulators. In this talk we will discuss the prospects of using OVs to improve tumor delivery of BiTEs, avoid off-tumor toxicities and possibly achieve synergistic anti-tumor effects.

9:20 Targeted Immunocytokines
Alessandra Villa, PhD, Head of Antibody Research, Philochem AG
Antibody-cytokine fusion proteins are increasingly being considered for the therapy of cancer, of chronic inflammatory conditions and of other debilitating diseases. In this talk, we show the preclinical development and the clinical performance of targeted cytokines for cancer therapy and beyond.

9:40 Landing on the Moon with Mass Spectrometry: Polyclonal Sequencing with Only Proteomics
Anthony Stajduhar, Director of International Business Development, Rapid Novor, Inc
Over the past 5 years Rapid Novor has perfected monoclonal antibody sequencing, and is now sequencing mAbs from polyclonal mixtures using REpAb®. After successfully launching their proteogenomics based sequencing technology to deconvolute the immune response, the team has further evolved the technology and has derived the most abundant mAb sequences directly from rabbit blood using only proteomics. The talk will surround the development, progress and use cases for REpAb®.

10:10 LIVE PANEL DISCUSSION: Not Your Average Bispecific Antibody: Innovative Formats and Triggered Bispecifics
Moderator: Frank Comer, PhD, Associate Principal Scientist, AstraZeneca
Panelists:
Christine E. Engeland, MD, PhD, Researcher Medical & Translational Oncology, Tumor Diseases Center, German Cancer Research Center, DKFZ
Alessandra Villa, PhD, Head of Antibody Research, Philochem AG
Anthony Stajduhar, Director of International Business Development, Rapid Novor, Inc

10:40 LIVE PANEL DISCUSSION: Bispecific Antibodies vs CAR Ts: Are they Competing Approaches or Complementary?

Moderator: David J. DiLillo, PhD, Associate Director, Regeneron Pharmaceuticals Inc.

1. Are there clinical circumstances where either CAR T or bispecifics may perform better or worse?
2. Toxicity and cytokine release syndrome:
3. Relative durability of CAR T and Bispecifics
4. Relative quality of effector cells for CAR T vs. Bispecifics:

Panelists:
Adrian Bot, PhD, Vice President and Global Head, Translational Medicine, Kite Pharma, a Gilead Company
Christian Klein, PhD, Cancer Immunotherapy Discovery, Roche Innovation Center Zurich, Roche Pharma Research & Early Development, pRED
G. Jonah Rainey, PhD, Vice President, Antibody Engineering, Alivamab Discovery Services
Michael Hudecek, MD, Professor, Cellular Immunotherapy of Malignant Diseases, University of Wuerzburg

11:10 Session Break - View Our Virtual Exhibit Hall

11:10 CO-PRESENTATION: ASK THE EXPERT with SCIEX

Matt Stone, Biologics Workflow Specialist, SCIEX
Mukesh Malik, Sr. Application Scientist, SCIEX

Join SCIEX analytical technology experts Matthew Stone and Mukesh Malik during an interactive Q&A session to discuss analytical development and optimization of capillary electrophoresis and liquid chromatography-mass spectrometry based methods for protein characterization and quantification. Exciting topics covered include mAbs and mAb variants, cell and gene therapy, vaccines and more!

YOUNG SCIENTIST KEYNOTE

11:25 Young Scientist Keynote Introduction

Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute

11:30 KEYNOTE PRESENTATION: Cryo-Electron Microscopy Structures of Spike Glycoproteins Suggest Pan-Coronavirus Antiviral Strategy

Christine Toelzer, Research Associate, University of Bristol, United Kingdom

We research antivirals to combat present and future coronavirus pandemics. We discovered linoleic acid bound to a hydrophobic pocket in the Cryo-EM structure of the SARS-CoV-2 Spike glycoprotein. Ligand binding locked the protein in a compact closed conformation. Conservation of key AA residues suggested a similar pocket exists in other pathogenic coronaviruses.

12:00 pm Live: Q&A with Young Scientist Keynote

Moderator: Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute
Panelists:
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

12:10 Session Break - View Our Virtual Exhibit Hall

1:00 Close of Advancing Bispecific Antibodies Conference

3:30 SC3: Developability of Bispecific Antibodies: Formats and Applications

Separate registration required. See short course page for details.

ENGINEERING BISPECIFIC ANTIBODIES

Constructing the Next Generation of Therapeutics

WEDNESDAY, MAY 12

YOUNG SCIENTIST KEYNOTE

11:25 am Young Scientist Keynote Introduction
Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute

11:30 KEYNOTE PRESENTATION: Cryo-Electron Microscopy Structures of Spike Glycoproteins Suggest Pan-Coronavirus Antiviral Strategy
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

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12:00 pm Live: Q&A with Young Scientist Keynote
Moderator: Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute
Panelists:
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

12:10 Session Break - View Our Virtual Exhibit Hall

T CELL ENGAGING BISPECIFICS: UNDERSTANDING AND ADDING SIGNALS TO CELL ENGAGERS

1:10 KEYNOTE PRESENTATION: Tackling AIDS and Cancer with Trispecific Antibodies
Gary J. Nabel, MD, PhD, President and CEO Co-Founder, ModeX Therapeutics

In an effort to improve the treatment of latent HIV infection, trispecific abs are being engineered to direct T lymphocytes to virally infected cells, activate latent viral gene expression, and potentiate killing of infected T cells.

1:30 Simultaneous Multiple Interaction T Cell Engaging (SMITE) Bispecifics to Overcome Drug Resistance Via CD28 Co-Stimulation
Roland B. Walter, MD, PhD, MS, Associate Professor, Clinical Research Division, Fred Hutchinson Cancer Research Center

Pairs of T cell-directed BiAbs (Simultaneous Multiple Interaction T-Cell Engaging [SMITE] bispecifics), which engage cancer-associated antigen(s) and provide CD28 co-stimulation, improve BiAb efficacy in a tumor cell-dependent fashion *in vitro* in preclinical tumor models. As shown with PD-L1 as example, SMITE bispecifics can transform checkpoint inhibition into T cell activation to overcome BiAb resistance.

1:50 Tumor-Specific Fc-Free 4-1BB-Agonistic Trimerbodies Displays Non-Toxic Anti-Tumor Activity
Luis M. Alvarez-Vallina, PhD, Group Leader, Immuno Oncology & Immunotherapy Group, Unidad de Immunoterapia del Cancer UNICA

We have generated tumor-targeted Fc-free trimerbodies targeting a tumor-associated antigen, such as EGFR or CEA, and 4-1BB in an agonistic manner. Both trimerbodies were potent co-stimulators *in vitro* and showed enhanced tumor penetration and powerful anti-tumor activity *in vivo*, while alleviating liver toxicities that are associated with IgG-based 4-1BB agonists. These results promote the use of the non-canonical trimerbodies for safe and effective costimulatory strategies in cancer immunotherapy.

2:10 Human Costimulatory Bispecific Antibodies in Cancer Immunotherapy
Dimitris Skokos, PhD, Senior Director, Cancer Immunology, Regeneron Pharmaceuticals

We developed a class of bispecific antibodies that mimic signal 2, by bridging a second TSA to a co-stimulatory receptor (CD28) on T cells. Combining this novel class of co-stimulatory bispecific antibodies with PD-1 mAb or the emerging class of TSAxCD3 bispecifics may provide well-tolerated, "off-the-shelf" antibody therapies with potentially enhanced anti-tumor efficacy.

2:30 Enhancing T Cell Engager Activity with Targeted CD28 Costimulation and Other Modalities
John R. Desjarlais, PhD, CSO, Xencor, Inc.

While classic CD3-binding T cell engagers are potent modalities, there may be need to enhance their activity in certain settings, including solid tumors. To this end, we have created a second class of TCEs that target the costimulatory receptor CD28 on T cells, promoting IL2 secretion and other enhancements. We have also explored combinations with other agents, including various cytokines and novel TGF inhibitors.

2:50 Unique *in vitro* Technologies for R&D of Biologics Including scFv, Fab, IgG and Cyclic Peptide
Takashi Ebihara, PhD, COO, GeneFrontier Corporation

Our unique platform technology called PURExfrex is a fully reconstituted (or rebuilt) cell-free protein expression system. PURExfrex can effectively express scFv, Fab and full IgG as well, which is useful for high throughput screening. In addition to that, we established robust ribosome display with customized PURExfrex called PURExfrexRD, which has great advantage in screening of highly diversified library and developing new antibodies or cyclic peptides.

3:10 Session Break

3:20 LIVE PANEL DISCUSSION: T Cell Engaging Bispecifics: Understanding and Adding Signals to T Cell Engagers
Moderator: G. Jonah Rainey, PhD, Vice President, Antibody Engineering, Alivamab Discovery Services
Panelists:
Gary J. Nabel, MD, PhD, President and CEO Co-Founder, ModeX Therapeutics
Roland B. Walter, MD, PhD, MS, Associate Professor, Clinical Research Division, Fred Hutchinson Cancer Research Center
Luis M. Alvarez-Vallina, PhD, Group Leader, Immuno Oncology & Immunotherapy Group, Unidad de Immunoterapia del Cancer UNICA
Dimitris Skokos, PhD, Senior Director, Cancer Immunology, Regeneron Pharmaceuticals
John R. Desjarlais, PhD, CSO, Xencor, Inc.
Takashi Ebihara, PhD, COO, GeneFrontier Corporation

3:40 PEGS Connects - View Our Virtual Exhibit Hall

3:30 SC3: Developability of Bispecific Antibodies: Formats and Applications
Separate registration required. See short course page for details.

4:00 Close of Day

THURSDAY, MAY 13

WHICH CELL TYPE IS THE MOST APPROPRIATE FOR ENGAGEMENT WITH THE IMMUNE SYSTEM? ALL OF THE ABOVE

9:00 am Novel Bispecific Gamma-Delta T Cell Engagers for the Treatment of Cancer

Paul Parren, PhD, Executive Vice President & Head, Lava Therapeutics

LAVA is developing a bispecific antibody T cell engager platform that leverages the unique qualities of γδ effector T cells. LAVA's bispecific γδ T cell engagers have been selected to create a wide therapeutic window with high activity against tumor cells whilst leaving healthy cells unharmed. LAVA's lead program will enter the clinic in Q1 2021. Recent preclinical development data including potency, mechanism of action and safety will be discussed.

9:20 CAR-Macrophages: A Novel Approach to Solid Tumor Immunotherapy

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

This presentation will describe the challenges solid tumors impose upon cell therapies and how myeloid cells (monocytes and macrophages) may overcome these barriers. The CAR-M concept will be described, and a preclinical dataset that describes this novel immunotherapy in depth will be presented.

9:40 CO-PRESENTATION: Picobodies™ as building blocks for novel therapeutics

OmniAb

Bill Harriman, Sr. Vice President, Antibody Discovery, Ligand Pharmaceuticals

Vaughn Smider, Founder, Taurus Biosciences, Ligand Pharmaceuticals

At 4-6 KD, "picobodies™" represent the smallest known Ig-derived binding moiety capable of high affinity interactions with target proteins. Their compact size offers excellent potential for the development of novel multispecific therapeutic molecules. As a case study, we have recovered a panel of broadly neutralizing ultra-long H3 SARS-CoV2 antibodies from immunized cows. The full length bovine antibodies, as well as their corresponding picobodies, demonstrate potent *in vitro* neutralization activity against all major viral variants.

10:10 LIVE PANEL DISCUSSION: Which Cell Type is the Most Appropriate for Engagement with the Immune System? All of the Above

Moderator: Eugene A. Zhukovsky, PhD, CSO, Biomunex Pharmaceuticals
Panelists:
Paul Parren, PhD, Executive Vice President & Head, Lava Therapeutics
Michael Klichinsky, PharmD, PhD, Co-Founder & Vice President, Discovery, Carisma Therapeutics
Bill Harriman, Sr. Vice President, Antibody Discovery, Ligand Pharmaceuticals
Vaughn Smider, Founder, Taurus Biosciences, Ligand Pharmaceuticals

NOVEL AGENTS FOR THERAPY AND IMAGING

10:30 Bispecific, Brain-Penetrating Antibodies for *in Vivo* Imaging and Therapy in Mouse Models of Alzheimer's Disease

Dag Sehlin, PhD, Associate Professor, Public Health and Caring Sciences, Uppsala University

My talk will describe how we use various bispecific antibodies, engineered to enter the brain via receptor-mediated transcytosis, to visualize and quantify amyloid-beta pathology in the brain of living mice, using PET and SPECT imaging. We also use these imaging techniques in the context of amyloid-beta directed therapy, either to quantify the effect of treatment or to localize therapeutic antibody in the brain over time.

10:50 Preclinical Evaluation of MCLA-129: A Bispecific Antibody Targeting c-MET and EGFR

Cecile Geuijen, PhD, Vice President Oncology Cell Biology, Merus NV

MCLA-129 is a full-length, IgG Biclonics® binding to EGFR and c-MET, capable of overcoming c-MET-dependent EGFR TKI resistance mechanisms following ligand-induced signaling. MCLA-129 is glycoengineered to enhance its Fc mediated ADCC and ADCP activity thus allowing it to inhibit tumor growth independent of EGFR or c-MET signaling. MCLA-129 holds promise as a potential treatment option for NSCLC and other solid tumors.

11:10 Session Break - View Our Virtual Exhibit Hall

LIVE PLENARY PANEL

11:30 Live Plenary Panel: Antibody and Vaccine Development for COVID-19




Moderator: Erica Ollmann Saphire, PhD, Professor, La Jolla Institute for Immunology

- What didn't go well during the pandemic?
- What is the future? Will there be an mRNA vaccine for influenza?
- What did we learn about our country's ability to manufacture during surge production?
- What is needed in terms of infrastructure?

Panelists:
Peter Hotez, MD, PhD, FASTMH, FAAP, Dean, National School of Tropical Medicine; Professor, Departments of Pediatrics, Molecular Virology & Microbiology; Co-Head, Section of Pediatric Tropical Medicine; Health Policy Scholar, Baylor College of Medicine
Lakshmi Krishnan, PhD, A/Vice-President, Life Sciences, National Research Council Canada, Government of Canada
Peter W. Marks, MD, PhD, Director, FDA CBER

12:15 pm Session Break - View Our Virtual Exhibit Hall

BREAKOUT DISCUSSIONS

12:30 Problem Solving Discussions

Join your colleagues and fellow delegates for a focused, informal discussion moderated by a member of our speaking faculty. A small group format allows participants to meet potential collaborators, share examples from their own work and discuss ideas with peers. See website for a full list of topics.

TABLE: T Cell Engaging Bispecifics: Understanding and Adding Signals to T Cell Engagers

G. Jonah Rainey, PhD, Vice President, Antibody Engineering, Alivamab Discovery Services

- What we know (and don't know) about the signaling associated with T cell activation by TCE
- Bispecific antibody approaches to add signal 2 through additional bispecific antibody targeting 41BB or CD28
- Combination with TNFRs and CPIs

1:10 Session Break - View Our Virtual Exhibit Hall

NOVEL AGENTS FOR THERAPY AND IMAGING

1:20 KEYNOTE PRESENTATION: A Self-Assembling and Disassembling (SADA) Multispecific Antibody Platform for Drug Delivery – Proof of Principle in Curative 2-Step Pre-Targeted Radioimmunotherapy

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

We developed a novel antibody platform called SADA that uses unique pharmacokinetics to dramatically improve TI and substantially reduce drug immunogenicity. When applied to pretargeted radioimmunotherapy (PRIT), bispecific SADA antibodies visualized tumors with high precision using PET (diagnostic) and ablated aggressive solid tumors using 177Lu or 225Ac (therapeutic), without any toxicity to bone marrow, liver, kidney or CNS.

1:40 Optimizing Multi-Specific Antibody Design with Mechanistic Avidity Models

Lucia Wille, PhD, Director & Head Biology, Applied BioMath LLC

Avid binding of multi-specific antibodies can confer desirable therapeutic properties, such as increased specificity to target cells. However, the design requirements and experimental interpretation are often counterintuitive. Mechanistic models provide clarity to guide development decisions (single-arm affinities, dosing) for desired functionality.

2:00 Development of [89Zr] ZrDFO-amivantamab Bispecific to EGFR and c-MET for PET Imaging of Triple-Negative Breast Cancer

Bernadette V. Marquez-Nostra, PhD, Assistant Professor, PET Center, Yale University

PET imaging with 89Zr-labeled antibodies is a non-invasive way to assess target engagement *in vivo*. Amivantamab, a bispecific antibody that targets EGFR and c-MET was developed as a companion PET imaging agent by radiolabeling with 89Zr. A comprehensive characterization of 89Zr-amivantamab in preclinical models of triple negative breast cancer will be discussed.

2:20 CO-PRESENTATION: Early Developability and Analytical Toolbox for the Production of Multi-chain Biotherapeutics

Lonza

Rebecca Michael, PhD, PhD - Principal Group Leader, Cell and Molecular Biology Group, Lonza

Karl Rogerson, Senior Principal Scientist, Global Process and Analytical Development Sciences, Lonza

In recent years the number of biotherapeutic molecules requiring more complex assemblies has greatly increased. Typically, these multi-chain molecules are no longer compatible with platform approaches and require a more agile approach to early developability and method development. Lonza have developed a Toolbox approach using *in silico* tools, vector design/screening and analytical method development that allows us to screen for titre and product assembly at an early stage of development.

2:50 LIVE PANEL DISCUSSION: Novel Agents for Therapy and Imaging

Moderator: Mahiuddin Ahmed, PhD, President and CSO, VITRUVIAE

Panelists:

Dag Sehlin, PhD, Associate Professor, Public Health and Caring Sciences, Uppsala University

Cecile Geuijen, PhD, Vice President Oncology Cell Biology, Merus NV

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

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Karl Rogerson, Senior Principal Scientist, Global Process and Analytical Development Sciences, Lonza

3:30 Close of Conference

IMMUNOTHERAPY STREAM

Developing Novel, Targeted Immunotherapies for Cancer and Immune Disorders

The Immunotherapy stream highlights the most exciting tools, technologies and engineering strategies driving the development of cellular and non-cellular immunotherapies for cancer and immune disorders. Part One examines recent breakthroughs in T cell biology, protein engineering and novel IO targets, plus new approaches for improving immunotherapy efficacy and safety. Part Two discusses the latest developments in cellular immunotherapy such as CAR Ts, TCRs, NKs, and TILs, including innovations in allogenic cellular therapy, gene editing and targeting, all supported by in-depth case studies and clinical data.

2021
IMMUNOTHERAPY
STREAM CONFERENCES

May 11-12

Improving Immunotherapy Efficacy and Safety

AGENDA

May 12-13

CAR Ts, TCRs and TILs

AGENDA

PEGSBOSTON
CONFERENCE STREAMS

- ENGINEERING
- ONCOLOGY
- BISPECIFIC ANTIBODIES
- IMMUNOTHERAPY
- EXPRESSION
- ANALYTICAL
- IMMUNOGENICITY
- COVID INTERVENTIONS

MAY 11-12, 2021 | 6th Annual

IMPROVING IMMUNOTHERAPY EFFICACY AND SAFETY

Engineering Strategies to Develop Targeted, Effective and Safe Immunotherapies

TUESDAY, MAY 11

PROGRESS IN IMMUNOTHERAPY

9:00 am KEYNOTE PRESENTATION: Cancer Immunotherapy: Reaching Stardom, But Where Does It Go From Here?

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

Immunotherapy has become front and center in our armamentarium against cancer, but, where do we go from here, especially given the need for combination therapies to really push the needle in terms of long-term patient survival? In this talk we will try to separate the hype from the reality summarizing the current landscape of cancer immunotherapy, new trends emerging, and some of the key challenges still ahead.

9:20 Update on the Next Generation of Immuno-Oncology Treatments

Haijun Sun, PhD, Head, Antibody Pharmacology, GlaxoSmithKline

New therapies that promote anti-tumor immunity have revolutionized the way patients are treated. This talk will give a description of the discovery and characterization of a monoclonal antibody targeting CD96. It will go into more detail on the opportunities, and how anti-CD96 differs from other agents as an innovative biologics to activate immune system to fight cancer.

9:40 NKTR-255, an Engineered IL-15 that Expands NK Cells and CD8+ T Cells for the Treatment of Cancer

Willem Overwijk, PhD, Vice President, Oncology Research, Nektar Therapeutics, Inc.

NKTR-255 is an engineered version of native IL-15, designed to have an improved pharmacokinetic profile, preserved binding to all endogenous IL-15 receptors, and to safely increase the proliferation, activity and survival of NK cells and memory CD8+ T cells. We will present preclinical and early clinical data of NKTR-255 in settings of advanced cancer.

10:00 IL-6 Blockade Mitigate Anti-CTAL-4 Toxicity While Improving Anti-Tumor Immunity

Adi Diab, MD, Associate Professor, Melanoma Medical Oncology, MD Anderson Cancer Center

10:20 Specificity screening of Mabs, scFvs & CAR Ts against expressed receptors, heterodimers & secreted protein targets

Nick Brown, MSc, Senior North American Business Development Manager, Retrogenix Limited

Cell microarray screening of plasma membrane and tethered secreted proteins that are expressed in human cells enables rapid discovery of primary receptors as well as potential off-targets for a variety of biologics including: peptides, antibodies, proteins, CAR T and other cell therapies. Case studies will demonstrate the power of the technology for identifying novel, druggable targets as well as for IND-enabling specificity screening and safety assessment.

10:50 LIVE PANEL DISCUSSION: Emerging Trends in Immunotherapy

Moderator: Laszlo G. Radvanyi, PhD, President & Scientific Director, Ontario Institute for Cancer Research
Panelists:
Haijun Sun, PhD, Head, Antibody Pharmacology, GlaxoSmithKline
Willem Overwijk, PhD, Vice President, Oncology Research, Nektar Therapeutics, Inc.
Adi Diab, MD, Associate Professor, Melanoma Medical Oncology, MD Anderson Cancer Center
Nick Brown, MSc, Senior North American Business Development Manager, Retrogenix Limited

11:10 Session Break - View Our Virtual Exhibit Hall

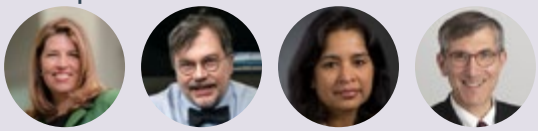
11:10 ASK THE EXPERT with Svar Life Science

Michael G. Tovey, Ph.D, Chief Scientific Advisor of Svar Life Science France, Svar Life Science

Svar´s Expert session will focus on AAV mediated gene therapy and potential neutralizing antibody response to AAV vectors. We know the importance of precisely quantify both the neutralizing antibody response prior to treatment, and the neutralizing antibody response to the recombinant AAV vector following treatment. Talk to us about how our highly sensitive reporter-gene assays are used for the quantification of NAbs to recombinant AAV vectors with different capsid specificities.

LIVE PLENARY PANEL

11:30 Live Plenary Panel: Antibody and Vaccine Development for COVID-19



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Lakshmi Krishnan, PhD, A/Vice-President, Life Sciences, National Research Council Canada, Government of Canada
Peter W. Marks, MD, PhD, Director, FDA CBER

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BREAKOUT DISCUSSIONS

12:20 Problem Solving Discussions

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TABLE: Immunotherapy Safety and Toxicity

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

1:00 Session Break - View Our Virtual Exhibit Hall

INNATE IMMUNITY, NK CELLS AND COMBINATIONS

1:10 Targeting Soluble NKG2D Ligands to Remodulate Tumor Microenvironment and Enhance the Response to Immunotherapy

Jennifer Wu, PhD, Mary and Patrick Scanlan Professor of Urology, Professor of Immunology, Feinberg School of Medicine, Robert Lurie Comprehensive Cancer Center, Northwestern University

Oncogenic-induced, membrane-bound NKG2D ligands stimulate NK and Cd8 T cell anti-tumor immunity. Conversely, tumor-edited soluble NKG2D ligands in the tumor microenvironment suppress anti-tumor immunity via multiple mechanisms. Here we present evidence that tumors shed soluble NKG2D ligand, the soluble MHC I chain-related molecule (sMIC), facilitates immune suppression of MDSCs. We also present evidence that targeting soluble MIC reprograms MDSC and primes the tumor immune microenvironment.

1:30 The Roles of Innate Immunity in Cancer Combination Therapies

Liming Liu, MD, PhD, President and CEO, Parr Biopharmaceuticals Ltd.

Immune checkpoint inhibitors (ICI) such as anti-PD1/PDL1 have revolutionized cancer treatments. However, only 10-30% of patients benefit from the treatment because of the complexity of tumor microenvironment (TME), which is usually "cold," and only "hot" tumors could be successfully treated by ICI. Many efforts including targeting innate immunity to turn the TME from "cold" to "hot" have been pursued and will be discussed.

1:50 KEYNOTE PRESENTATION: Engineering Pluripotent Stem Cell Derived NK Cells for Improved Function

Dan S. Kaufman, MD, PhD, Professor Medicine & Director, Cell Therapy Program, University of California San Diego

Human pluripotent stem cells provide a key resource for cellular immunotherapies. Our group has demonstrated that NK cells can be efficiently derived from both hESCs and iPSCs. This system provides a platform to express CARs and other engineering strategies to produce immune cells with enhanced anti-tumor activity. hESC/iPSC-derived NK cells can be expanded to clinical scale in GMP-compatible conditions.

2:10 Targeting NK Cells to Treat Cancer: Individual to Off-the-Shelf Products

Jeffrey Miller, MD, Professor of Medicine, Deputy Director, Masonic Cancer Center, Division of Hematology, Oncology and Transplantation, University of Minnesota

NK cells can achieve complete remission in patients with refractory AML. Limitations of current NK cell strategies include single donor products, allogeneic persistence, and tumor specificity. To enhance specificity, trispecific killer engagers can be used alone or with adoptive transfer. NK cell multi-dosing will be achieved with off-the-shelf, genetically modified, induced pluripotent stem cells overexpressing CD16 or CAR with an endogenous IL-15 signal to enhance persistence.

2:30 Assessing Efficacy and Potential Safety Risks Cell Therapies *in Vitro* Using Primary and Ipsc-Derived Cells

Sophie Vermond, Early Discovery Scientist, Immunology, Immuno-oncology and Cell Therapy, Charles River

Within cell therapy development the use of *in vivo* animal models can present significant hurdles in translatability to humans. As a result, the establishment of complementary high-quality *in vitro* efficacy and safety studies to foster the development of such therapies has become critical before filing for Investigational New Drug (IND) status. Charles River has developed an *in vitro* efficacy package aimed at determining cell therapy activity, specificity and potency. In addition, we are able to generate an *in vitro* safety profile using primary and iPSC-derived cells.

2:50 Proteins and Reagents for Cell and Gene Therapy Research

Deborah Moore-Lai, Director of Protein Development, Abcam

Cell and gene therapy research requires the highest quality reagents as possible to achieve optimal experimental results. Abcam offers a broad portfolio of recombinant proteins and assays to enable & support research in the cell and gene therapy spaces. During this talk, we will share one of our latest new product offerings, our industry-leading premium proteins, which have the highest quality standards available, and present a few key proteins for cell and gene therapy research.

3:20 LIVE PANEL DISCUSSION: Controlling and Manipulating the Innate Immune System

Moderator: Jeffrey Miller, MD, Professor of Medicine, Deputy Director, Masonic Cancer Center, Division of Hematology, Oncology and Transplantation, University of Minnesota

Panelists:

Jennifer Wu, PhD, Mary and Patrick Scanlan Professor of Urology, Professor of Immunology, Feinberg School of Medicine, Robert Lurie Comprehensive Cancer Center, Northwestern University

Liming Liu, MD, PhD, President and CEO, Parr Biopharmaceuticals Ltd.

Dan S. Kaufman, MD, PhD, Professor Medicine & Director, Cell Therapy Program, University of California San Diego

Lisa Scandiuzzi, PhD, Senior Scientist, Charles River

Deborah Moore-Lai, Director of Protein Development, Abcam

3:40 PEGS Connects - View Our Virtual Exhibit Hall

4:00 Close of Day One

3:30 SC1: CAR T Cell Therapy from A-Z SC2: Introduction to Gene Therapy Products Manufacturing and Analytics

Separate registration required. See short course page for details.

WEDNESDAY, MAY 12

ENHANCING IMMUNOTHERAPY EFFICACY AND RESPONSE

9:00 am Improving Immunotherapy Safety and Response

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

Despite the unprecedented activity of CAR T cell therapy, the wider application is limited by the development of life-threatening toxicities of cytokine release syndrome and neurotoxicity. Here we will review new insights into the mechanisms of these toxicities and novel strategies to enhance CAR T cell safety.

9:20 Redirecting Cytotoxic T Cells with Chemically Programmed Antibodies

Christoph Rader, PhD, Professor, Immunology & Microbiology, The Scripps Research Institute

Chemically programmed T cell engaging bispecific antibodies combine (i) a small molecule that targets a cancer cell surface receptor and (ii) an antibody that recruits and activates T cells. Conceptually similar, chimeric antigen receptor T cells can also be put under the control of a small molecule by using a chemically programmed antibody as a switch. As such, chemically programmed antibodies can endow small molecules with the power of cancer immunotherapy.

LATEST DEVELOPMENTS IN TCR-BASED THERAPIES

9:40 Discovery and Development of TCR-Like Antibodies in Cancer Immunotherapy

Dongxing Zha, PhD, Institute Head, ORBIT Platform, MD Anderson Cancer Center

To mimic T cell receptors recognizing fragments of antigen as peptides bound to major histocompatibility complex (MHC) molecules, the ORBIT platform at MD Anderson develops technology in discovery of antibody specific to tumor MHC complex, and antibody leads are further engineered into suitable modalities like bispecific Ab and CAR T for selected targets. We will discuss multiple examples of TCR like antibody programs.

10:00 Staying on Target: Tuning pHLA-Specific Reagents in Cancer Immunotherapy

David Cole, PhD, Associate Director of Disease Biology Oncology, Immunocore, Honorary Senior Research Fellow, Cardiff University

Immunotherapy approaches that target peptide-human leukocyte antigen (pHLA) complexes have the potential to access virtually all foreign/cellular proteins. Consequently, several protein engineering solutions have been applied to the natural ligand for pHLA, the T cell receptor (TCR), to enhance both its stability and affinity as a soluble drug. Here, the molecular consequences of these modifications on TCR target-selectivity are considered, with obvious implications for target-fidelity in the clinic.

10:20 Identify and Select Optimal T Cell Phenotypes

James Lovgren, Vice President, Cell Therapy, Marketing, Berkeley Lights, Inc.

Understanding the underlying mechanisms of T cell differentiation and function is critical for developing effective therapeutics. However, T cells are extremely heterogeneous and have variable responses to stimulation. This makes predicting specific T cell responses extremely difficult. To identify effective T cells within a heterogeneous sample, scientists must be able to characterize T cells at the single-cell level. However, most existing single-cell methods are destructive and prevent the correlation of cytokine secretion with other functional parameters like cytotoxicity or gene expression. Here we share use cases that demonstrate how the Opto™ Cell Therapy Development workflow makes it possible to fully characterize individual T cells, correlate key characteristics, and directly link phenotype to gene expression at a single-cell level — all on the same T cells — enabling the development of more efficacious therapies.

10:50 LIVE PANEL DISCUSSION: Improving Immunotherapy Safety and Efficacy, TCR-based Therapies

Moderator: Saad Kenderian, PhD, Assistant Professor, Medicine and Oncology, Mayo Clinic College of Medicine
Panelists:
Christoph Rader, PhD, Professor, Immunology & Microbiology, The Scripps Research Institute
Dongxing Zha, PhD, Institute Head, ORBIT Platform, MD Anderson Cancer Center
David Cole, PhD, Associate Director of Disease Biology Oncology, Immunocore, Honorary Senior Research Fellow, Cardiff University
James Lovgren, Vice President, Cell Therapy, Marketing, Berkeley Lights, Inc.

11:10 Session Break - View Our Virtual Exhibit Hall

11:10 CO-PRESENTATION: ASK THE EXPERT with SCIEX

Matt Stone, Biologics Workflow Specialist, SCIEX
Mukesh Malik, Sr. Application Scientist, SCIEX

Join SCIEX analytical technology experts Matthew Stone and Mukesh Malik during an interactive Q&A session to discuss analytical development and optimization of capillary electrophoresis and liquid chromatography-mass spectrometry based methods for protein characterization and quantification. Exciting topics covered include mAbs and mAb variants, cell and gene therapy, vaccines and more!

YOUNG SCIENTIST KEYNOTE

11:25 Young Scientist Keynote Introduction

Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute

11:30 KEYNOTE PRESENTATION: Cryo-Electron Microscopy Structures of Spike Glycoproteins Suggest Pan-Coronavirus Antiviral Strategy

Christine Toelzer, Research Associate, University of Bristol, United Kingdom

We research antivirals to combat present and future coronavirus pandemics. We discovered linoleic acid bound to a hydrophobic pocket in the Cryo-EM structure of the SARS-CoV-2 Spike glycoprotein. Ligand binding locked the protein in a compact closed conformation. Conservation of key AA residues suggested a similar pocket exists in other pathogenic coronaviruses.

12:00 pm Live: Q&A with Young Scientist Keynote

Moderator: Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute
Panelists:
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

12:10 Session Break - View Our Virtual Exhibit Hall

1:00 Close of Improving Immunotherapy Efficacy and Safety Conference

MAY 12-13, 2021 | 8th Annual

CAR Ts, TCRs AND TILs

Engineering Strategies to Advance Cellular Immunotherapies

WEDNESDAY, MAY 12

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12:00 pm Live: Q&A with Young Scientist Keynote
Moderator: Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute
Panelists:
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

12:10 Session Break - View Our Virtual Exhibit Hall

CAR TS FOR B CELL MALIGNANCIES: TOWARDS A CURE

1:10 KEYNOTE PRESENTATION: Tisa-Cel: Real World Outcomes across B Cell Malignancies
David L. Porter, MD, Professor & Director Cell Therapy & Transplantation, Hematology & Oncology, University of Pennsylvania

Trials using CAR T cells showed dramatic responses in relapsed/refractory B-ALL and NHL leading to FDA approval of 3 CAR T cell products as of Dec 2020. Tisagenlecleucel was approved Aug 2017 for ALL and May 2018 for NHL. It is critical to understand not just clinical trial results but real-world outcomes once these therapies are used commercially. This talk reviews accumulating data from real-world application of commercial tisagenlecleucel.

1:30 KEYNOTE PRESENTATION: Anti-CD19 CAR T Cell Treatment for Lymphoma: Getting Closer to the Cure
Adrian Bot, PhD, Vice President and Global Head, Translational Medicine, Kite Pharma, a Gilead Company

CAR T cell therapy against CD19 showed considerable promise in B cell malignancies. In Non-Hodgkin's lymphoma, evidence to date points to a subset of ≈40% of patients showing durable complete response years post-treatment, with evidence of normal B cell recovery. Detailed translational analysis uncovered product and tumor related features that may determine durable efficacy, with impact on next generation interventions.

1:50 KEYNOTE PRESENTATION: Lessons from the Early Days of CD19 CAR T Cell Therapy for B Cell Malignancies
Cameron J. Turtle, MBBS PhD, Associate Professor, Clinical Research Division, Fred Hutchinson Cancer Research Centre

Lymphodepletion followed by CD19 chimeric antigen receptor (CAR)-modified T cells is a novel therapy for relapsed and/or refractory B cell malignancies. Using data from a large clinical trial of CD19 CAR T cell therapy in adults, factors impacting outcomes such as clinical responses and toxicities will be presented.

2:10 Parallel CAR T Cell Immunotherapy of Refractory Cancer Types
John Maher, PhD, Consultant & Senior Lecturer, Immunology, Kings College London

2G CARs containing a CD28 or 41BB endodomain elicit remarkable efficacy in hematological malignancies. 3G CARs contain both co-stimulatory units, although impact has been muted. We postulated that effective dual co-stimulation requires juxta-membrane positioning of these domains within separate receptors. We demonstrate that such parallel CAR T-cells resist exhaustion and senescence, sustaining proliferation, cytokine release, cytokine signaling and metabolic fitness.

3:00 LIVE PANEL DISCUSSION: Latest Advances in CAR T Cell Therapy
Moderator: Adrian Bot, PhD, Vice President and Global Head, Translational Medicine, Kite Pharma, a Gilead Company
Panelists:
David L. Porter, MD, Professor & Director Cell Therapy & Transplantation, Hematology & Oncology, University of Pennsylvania
Cameron J. Turtle, MBBS PhD, Associate Professor, Clinical Research Division, Fred Hutchinson Cancer Research Centre
John Maher, PhD, Consultant & Senior Lecturer, Immunology, Kings College London

3:20 PEGS Connects - View Our Virtual Exhibit Hall

3:30 SC3: Developability of Bispecific Antibodies: Formats and Applications
Separate registration required. See short course page for details.

4:00 Close of Day

THURSDAY, MAY 13

NEW CAR T TARGETS AND APPROACHES

9:00 am New Targets and Technologies for CAR T
Michael Hudecek, MD, Professor, Cellular Immunotherapy of Malignant Diseases, University of Wuerzburg

This talk will feature novel mechanisms of resistance to CAR-T therapy, novel target antigens and CAR-T cell products for treating multiple myeloma, virus-free transposon-based gene-transfer for CAR-T manufacturing, and a novel application for CAR-T in fungal infections.

9:20 Putting CARs into Overdrive Using Autonomous Inducible Expression of Throttles and Safety Belts
Daniel J. Powell Jr., PhD, Associate Professor, Pathology & Laboratory Medicine, University of Pennsylvania

The next generation of CAR T cell therapy will rely on devising systems that improve efficacy and safety. Uni-Vect is a single vector system that permits transient expression of immunostimulatory cytokines or transcription factors to improve activity or CRS blocking antibody to improve safety, as well as screening of new immune receptors. UniVect offers a solution for more effective and safe next-generation cellular immunotherapies.

9:40 CRISPR-Based Enhancement of CAR T Activity
Marco Ruella, MD, Assistant Professor of Medicine, Scientific Director, Lymphoma Program, Division of Hematology and Oncology and Center for Cellular Immunotherapies, University of Pennsylvania

Dr. Ruella will discuss the recent developments in CAR T cell immunotherapy from his laboratory. He will discuss findings on the mechanisms of resistance to CART therapy and novel strategies to enhance CART functions. Finally, he will present recent data on the development of CART products for other hematological malignancies that do not express CD19.

10:00 Addressing the Repertoire of Gamma Delta Targets in Human Tumors

Daniel Olive, MD, PhD, Head, Tumor Immunology, Marseille Cancer Research Center

A key question regarding cell therapies and antibodies is the existence of targets recognized by gamma delta T cells. We will present an extensive study of gamma delta T cells and ligands in solid tumors and leukemias.

10:20 Tumor-effector cell interaction strength is a key driver for CAR T-cell function

Rogier Reijmers, PhD, Principal Scientist & Head of Validation Research, LUMICKS

While affinity of scFv is a poor predictor of CAR T-cell efficacy, overall binding strength (avidity) represents a crucial parameter for identifying and developing potent immunotherapies. Avidity reflects the bona fide interactions between T-cells and tumor cells and could therefore better predict effectiveness. The z-Movi® Cell Avidity Analyzer is a unique instrument for direct measurement of cellular avidity providing a novel method to accelerate cell immunotherapy.

10:50 LIVE PANEL DISCUSSION: New Engineering Approaches to CAR T Therapy

Moderator: Daniel J. Powell Jr., PhD, Associate Professor, Pathology & Laboratory Medicine, University of Pennsylvania
Panelists:
Michael Hudecek, MD, Professor, Cellular Immunotherapy of Malignant Diseases, University of Wuerzburg
Marco Ruella, MD, Assistant Professor of Medicine, Scientific Director, Lymphoma Program, Division of Hematology and Oncology and Center for Cellular Immunotherapies, University of Pennsylvania
Daniel Olive, MD, PhD, Head, Tumor Immunology, Marseille Cancer Research Center
Rogier Reijmers, PhD, Principal Scientist & Head of Validation Research, LUMICKS

11:10 Session Break - View Our Virtual Exhibit Hall

LIVE PLENARY PANEL

11:30 Live Plenary Panel: Antibody and Vaccine Development for COVID-19




Moderator: Erica Ollmann Saphire, PhD, Professor, La Jolla Institute for Immunology

- What didn't go well during the pandemic?
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Panelists:
Peter Hotez, MD, PhD, FASTMH, FAAP, Dean, National School of Tropical Medicine; Professor, Departments of Pediatrics, Molecular Virology & Microbiology; Co-Head, Section of Pediatric Tropical Medicine; Health Policy Scholar, Baylor College of Medicine
Lakshmi Krishnan, PhD, A/Vice-President, Life Sciences, National Research Council Canada, Government of Canada
Peter W. Marks, MD, PhD, Director, FDA CBER

12:15 pm Session Break - View Our Virtual Exhibit Hall

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12:30 Problem Solving Discussions

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TABLE: Next-Generation Cell-based Immunotherapies

Adrian Bot, PhD, Vice President and Global Head, Translational Medicine, Kite Pharma, a Gilead Company

1:10 Session Break - View Our Virtual Exhibit Hall

TARGETING SOLID TUMORS

1:20 Advancing Solid Tumor Immunotherapy Platforms

Saul J. Priceman, PhD, Assistant Professor, Hematology & Hematopoietic Cell Transplantation, City of Hope Beckman Research Institute

CAR-engineered T cell immunotherapy is under active investigation for the treatment of patients with advanced solid tumors, in light of the exceptional clinical responses seen in hematological malignancies, particularly CD19-targeting CAR T cells. However, major inhibitory mechanisms are hindering durable anti-tumor responses in solid tumors, which are addressing using novel combination therapies as well as innovative intrinsic editing approaches to improve overall anti-tumor immunity and durable therapeutic responses.

1:40 Development of an Allogeneic Anti-GD2 T Cell Therapy for Neuroblastoma Utilizing a Novel Dimeric Antigen Receptor (DAR) Structure

Wenzhong Guo, PhD, Vice President, Cell Therapy, Sorrento Therapeutics Inc.

Neuroblastoma remains an incurable malignancy. GD2 is highly expressed on neuroblastoma tissue. We have developed an allogeneic T cell therapy approach utilizing genetic engineering of donor-derived T cells to express an anti-GD2DAR. Preclinical data demonstrate DAR-T has superior anti-tumor activity both *in vitro* and *in vivo* against neuroblastoma compared to CAR T cells.

2:00 TIL Therapy: An Advanced Adoptive Cell Therapy Platform for the Treatment of Solid Cancers

John B.A. Haanen, MD, PhD, Professor, Translational Immunotherapy of Cancer, Leiden University Medical Center, Netherlands Cancer Institute

TIL therapy is a promising cell therapy approach. Both academic institutions and biotech companies have shown activity of TIL therapy in multiple cancer types, including melanoma, NSCLC, HPV-associated cancers, and others. TIL consists of deploying cancer-reactive tumor-infiltrated T cells, following *in vitro* re-activation and expansion, for therapy. Currently, of all cell therapies, TIL has been most successful. A randomized phase 3 trial in melanoma has almost finished accrual.

2:20 Investigating the Power of Tumor Infiltrating Lymphocytes for Treatment of Cancer

Maria Fardis, PhD, President & CEO, Iovance Biotherapeutics

Iovance is currently conducting pivotal studies in patients with metastatic melanoma and advanced cervical cancer. In addition, the company's TIL therapies are being investigated for the treatment of patients with locally advanced, recurrent or metastatic cancers including head and neck and non-small cell lung cancer. Clinical studies of T cell therapy for blood cancers called peripheral blood lymphocyte (PBL) therapy are being planned.

2:40 Moving to Commercial Readiness with a Dedicated Analytical Platform for T-cell Therapies

Dr. Jef Pinxteren, Director of Process and Analytical Development, Catalent Cell and Gene Therapy, Science and Development, Catalent Cell and Gene Therapy

Catalent will discuss a breadth of analytical methodologies facilitating manufacturing design and accelerating CAR-T therapies to commercial readiness phase.

Attendees will be able to gain insight into:

- Benefits of working with a full-service provider of analytical methods
- Strategy and process flow from analytical assay development to GMP implementation for clinical and commercial manufacturing

3:10 LIVE PANEL DISCUSSION: Cell-Based Immunotherapy Towards Solid Tumors

Moderator: Saul J. Priceman, PhD, Assistant Professor, Hematology & Hematopoietic Cell Transplantation, City of Hope Beckman Research Institute
Panelists:
John B.A. Haanen, MD, PhD, Professor, Translational Immunotherapy of Cancer, Leiden University Medical Center, Netherlands Cancer Institute
Maria Fardis, PhD, President & CEO, Iovance Biotherapeutics
Wenzhong Guo, PhD, Vice President, Cell Therapy, Sorrento Therapeutics Inc.
Dr. Jef Pinxteren, Director of Process and Analytical Development, Catalent Cell and Gene Therapy, Science and Development, Catalent Cell and Gene Therapy

3:30 Close of Conference

EXPRESSION STREAM

Increasing Productivity, Ensuring Quality

Meeting industry's growing demands for heterologous protein expression and production requires next-gen strategies and breakthrough research while developing and applying cutting-edge tools and technologies. The Expression Stream explores "Difficult-to-Express" proteins, including membrane and other especially troublesome proteins. "Optimizing Protein Expression" addresses production strategies by examining and enhancing expression systems. What is the best expression system for expressing your protein of choice? 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.

2021 EXPRESSION STREAM CONFERENCES

May 11-12

Difficult-to-Express Proteins

AGENDA

May 12-13

Optimizing Protein Expression

AGENDA

PEGSBOSTON CONFERENCE STREAMS

ENGINEERING | ONCOLOGY | BISPECIFIC ANTIBODIES | IMMUNOTHERAPY
EXPRESSION | ANALYTICAL | IMMUNOGENICITY | COVID INTERVENTIONS

REGISTER EARLY & SAVE!

TABLE OF CONTENTS

TUESDAY, MAY 11

OVERCOMING EXPRESSION CHALLENGES

9:00 am FEATURED PRESENTATION: Functional Expression of Adenosine A3 and A1 Receptors in Yeast Utilizing a Chimera with the A2AR C-Terminus

Anne Skaja Robinson, PhD, Professor & Head, Chemical Engineering, Carnegie Mellon University

The adenosine A_{2A} receptor ($A_{2A}R$) shows exceptional yields in all expression hosts, unlike the closely related G protein-coupled receptors A_1R and A_3R. By swapping the cytoplasmic C-terminus of $A_{2A}R$ we were able to create chimeric A_3R and A_1R proteins with increased yields that retain activity and native-like G-protein coupling. This strategy of utilizing chimeric receptor variants thus provides an exciting opportunity to improve active protein expression for "difficult-to-express" receptors.

9:20 A Rational Approach to Designing Cell-Free Synthesis-Based Biomolecule Platform Screening Processes

Beatrice Melinek, PhD, Bioprocess Engineer, University College London

Advances in cell-free protein synthesis (CFPS) offer the prospect of industrially relevant screening and even production processes, with the advantage of greater speed, control over process environment, integration into high-throughput systems and improved consistency. We present studies of how biochemical engineering approaches can be used to improve the titre and quality of a virus-like particle (VLP) protein product, by manipulation of process environment parameters and plasmid design.

9:40 Standard mAb ≠ Easy-to-Express: How the Production of Monoclonal Antibodies Can Turn Into a Difficult-to-Express Challenge

Valerie Schmieder, PostDoc, Cell Line Development, Bioprocess Development, Biologicals, Boehringer Ingelheim Pharma GmbH & Co. KG

Although mAbs are considered as standard molecules in biotherapeutic industry, some are still difficult-to-express. We highlight the development of a difficult-to-express monoclonal antibody and its challenges for CHO cell-line generation. Protein engineering and modulation of vector architecture are presented as approaches to improve product yields. A new cell-line development concept in CHO going beyond random transgene integration is highlighted to further boost the expression of a difficult-to-express molecule.

10:00 Improved Two-Stage Protein Production in Engineered *E. Coli*

Michael D. Lynch, PhD, Assistant Professor, Biomedical Engineering & Chemistry, Duke University

E. coli, the work horse host for protein production still faces many challenges in protein expression. 2-stage production enables the utilization of 2-stage dynamic control, wherein the cellular state can be modified (beyond conditions compatible with growth) to enable optimal protein expression, even with difficult to express proteins. Level of key proteases, chaperones and even the reduction potential of the cytoplasm can be dynamically controlled.

10:20 Get More Molecules to the Clinic Faster with Fully Integrated, Automated Opto™ Cell Line Development

BERKELEY LIGHTS

Renee Tobias, Director, CLD Product Management, Marketing, Berkeley Lights

In the new era of complex modalities and COVID-19 pandemic, speed, capacity, efficiency, and robustness are more vital than ever to a successful biotherapeutics development program. Yet CHO cell line selection still represents a painful, costly bottleneck - requiring weeks waiting for cells to expand and processing of hundreds of well plates. Learn how Opto™ CLD workflow on the Beacon® system integrates cell enrichment, cloning, culture, screening, and selection into a single, automated microscale process that generates the highest titer clones in just a few days. Case studies will highlight how users are accelerating and de-risking their path to IND with capacity for up to 50 campaigns per year, multiple molecules per campaign, and FDA-accepted monoclonality assurance to support regulatory submissions.

10:50 LIVE PANEL DISCUSSION: Overcoming Expression Challenges

Moderator: Anne Skaja Robinson, PhD, Professor & Head, Chemical Engineering, Carnegie Mellon University
Panelists:
Michael D. Lynch, PhD, Assistant Professor, Biomedical Engineering & Chemistry, Duke University
Beatrice Melinek, PhD, Bioprocess Engineer, University College London
Valerie Schmieder, PostDoc, Cell Line Development, Bioprocess Development, Biologicals, Boehringer Ingelheim Pharma GmbH & Co. KG
Renee Tobias, Director, CLD Product Management, Marketing, Berkeley Lights

11:10 Session Break - View Our Virtual Exhibit Hall

11:10 ASK THE EXPERT with Svar Life Science

SVAR

Michael G. Tovey, Ph.D, Chief Scientific Advisor of Svar Life Science France, Svar Life Science

Svar´s Expert session will focus on AAV mediated gene therapy and potential neutralizing antibody response to AAV vectors. We know the importance of precisely quantify both the neutralizing antibody response prior to treatment, and the neutralizing antibody response to the recombinant AAV vector following treatment. Talk to us about how our highly sensitive reporter-gene assays are used for the quantification of NAbs to recombinant AAV vectors with different capsid specificities.

PLENARY KEYNOTE ADDRESS

11:25 Plenary Keynote Introduction

Jennifer R. Cochran, PhD, Shriram Chair & Professor, Bioengineering & Chemical Engineering, Stanford University

11:30 KEYNOTE PRESENTATION: The Coming of Age of *de Novo* Protein Design

David A. Baker, PhD, Henrietta & Aubrey David Endowed Professor, Biochemistry, University of Washington

I will describe the *de novo* design of fluorescent proteins, membrane penetrating macrocycles, transmembrane protein channels, allosteric proteins that carry out logic operations, and self-assembling nanomaterials and polyhedra. I will also discuss the application of these methods to COVID-19 challenges.

12:00 pm Live: Q&A with Audience

Moderator: Jennifer R. Cochran, PhD, Shriram Chair & Professor, Bioengineering & Chemical Engineering, Stanford University
Panelists:
David A. Baker, PhD, Henrietta & Aubrey David Endowed Professor, Biochemistry, University of Washington

12:10 Session Break - View Our Virtual Exhibit Hall

BREAKOUT DISCUSSIONS

12:20 Problem Solving Discussions

Join your colleagues and fellow delegates for a focused, informal discussion moderated by a member of our speaking faculty. A small group format allows participants to meet potential collaborators, share examples from their own work and discuss ideas with peers. See website for a full list of topics.

TABLE: Ranking Product Attributes to Select an Appropriate Expression Platform

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

- Can you predict?
- When do you first know you got it right?
- When is it too late to change course?

1:00 Session Break - View Our Virtual Exhibit Hall

OVERCOMING PURIFICATION CHALLENGES

1:10 Optimizing the Purification Process of the Membrane Protein Bcl-2 for Structural Studies

Jorgen Aden, PhD, Principal Research Engineer, Chemistry, Umea University

The intrinsic pathway of programmed cell death is tightly regulated by the Bcl-2 protein family located at the mitochondrial outer membrane, controlling the release of apoptotic factors. For a long time, obtaining enough Bcl-2 membrane protein for biophysical studies was difficult, which demanded a more efficient purification protocol. This was finally solved by using a classical *Escherichia coli* expression system, increasing the yield to produce 10-20 mg of full-length protein.

1:30 Pseudomonas based platform for therapeutic protein production

PELICAN

Russell Coleman, Associate Director, Strain Engineering, Pelican Expression Technology

Pelican Expression Technology (formerly Pfenex) is a validated, cost-effective, and scalable platform for recombinant protein production and is well-suited for large-scale protein production, where traditional systems are not suitable. Learn how this Pseudomonas-based expression platform was developed for recombinant protein production. Case studies presented demonstrate the genetic elements, host strains, and automated strain screening workflows enabled broad exploration of expression strategies for two complex antibody scaffolds: Fab fragment and multimeric nanobodies.

1:50 Sane in the Membrane – Salipro One-Step Reconstitution of Membrane Proteins for Drug Development

Jens Frauenfeld, PhD, Founder & CEO, Salipro Biotech AB

Membrane proteins are important drug targets (GPCRs, ion channels), yet are notoriously difficult to work with. We have developed a novel one-step approach for the incorporation of membrane proteins directly from crude cell membranes into lipid Salipro particles. This direct approach termed Salipro DirectMX presents new opportunities for *de novo* development and characterisation of biologics and small molecules, including phage display, B-cell sorting and cryoEM.

2:10 Small Affinity Tags for Expression, Purification, and Biophysical Studies of G Protein-Coupled Membrane Receptors

Alexei Yeliseev, PhD, Staff Scientist, Group Leader, LMBB, NIH/NIAAA

Affinity tags have been widely applied to purification of G protein-coupled receptors (GPCR) for structural studies. We developed a novel calcium-dependent EF-based affinity system that allows capture and high recovery of GPCR from dilute solutions l. The binding of the EF1 tag to the resin is very strong (high picomolar to low nanomolar range) that allows efficient purification without any loss of the target protein.

2:30 Clone and process optimization – Combining productivity with quality goal

FyoniBio

Lars to Stöckl, Dr., Division Manager, FyoniBio - Service Branch of Glycotope

During the live cycle of a biopharmaceutical project the production needs to stay up to date with productivity and quality demands from early pre-clinical to market phase. Optimization can be done at different stages and on different levels with selecting the right cell line, selecting the right clone or optimizing the media/feed combination and / or optimizing process parameters. We provide case studies which address the different possibilities of optimization.

3:00 LIVE PANEL DISCUSSION: Overcoming Purification Challenges

Moderator: Alexei Yeliseev, PhD, Staff Scientist, Group Leader, LMBB, NIH/NIAAA

Panelists:

Jorgen Aden, PhD, Principal Research Engineer, Chemistry, Umea University

Jens Frauenfeld, PhD, Founder & CEO, Salipro Biotech AB

Gerhard Grobner, PhD, Senior Lecturer, Department of Chemistry, Umea University

Lars to Stöckl, Dr., Division Manager, FyoniBio - Service Branch of Glycotope

Russell Coleman, Associate Director, Strain Engineering, Pelican Expression Technology

3:20 PEGS Connects - View Our Virtual Exhibit Hall

4:00 Close of Day One

3:30 SC1: CAR T Cell Therapy from A-Z SC2: Intro to Gene Therapy Products Manufacturing & Analytics

Separate registration required. See short course page for details.

WEDNESDAY, MAY 12

OVERCOMING PRODUCTION CHALLENGES

9:00 am Protein Engineering and Process Mode for Successful Production of the Extracellular Domain of CD19

Renate Kunert, PhD, Department of Biotechnology, University of Natural Resources and Life Sciences (BOKU)

CD19 on malignant B cells constitutes the target of approved CAR T cell-based cancer immunotherapies. Assessment of CAR T cells is hampered by limited availability of CD19. We expressed a novel fusion construct consisting of the full-length extracellular domain of CD19 and domain two of human serum-albumin (CD19-AD2) in CHO and optimized production by continuous fermentation. Purified monomeric CD19-AD2 showed specificity to CAR T cells and activation of T cell function.

9:20 Protein Production: Dealing with the Unpredictable

Neesha Dedi, PhD, Senior Scientist, Protein Sciences, UCB Pharma

Often the first activity within a new project is the generation of protein reagents for assay development, antibody discovery or structural studies. Project timelines for such activities is challenging as it is almost impossible to predict how long it will take to express and purify a protein. Case studies highlighting the unpredictability of recombinant protein production and processes implemented at UCB to increase success are shared.

9:40 Corynex®: Suitable Protein Expression System for Antibody Mimetics

BIO•PHARMA SERVICES

Yoshihiko Matsuda, PhD, Principal Researcher, Research Institute for Bioscience Products & Fine Chemicals, Ajinomoto Co., Inc.

We have developed a unique recombinant protein secretion system by using Corynebacterium glutamicum and protein expression service Corynex®. It has some advantages such as the secretion of correctly folded and active form, high purity, and endotoxin-free. Recently, "Antibody mimetics" have been developing as well as conventional major antibodies, so we have examined the production of those proteins. We demonstrate Corynex® is very suitable system to produce various kinds of antibody mimetics.

10:00 Multi-Epitope Insert Modulates Solubility-based and Chromatographic Purification of Human Papilloma Virus 16 L1-based Vaccine without Inhibiting Virus-Like Particle Assembly

Mike Zhang, PhD, Professor, Biological Systems Engineering, Virginia Polytechnic Institute & State University

Protein purification has been made much easier by the incorporation of many different tags, but most tags don't have other functions beyond facilitating the purification. Here we show the modifications of a protein, recombinant human papilloma virus 16 L1 (rHPV 16 L1), that not only improve the purification of the modified protein but also afford the protein with desired immunological properties.

10:20 Fast and efficient recombinant protein expression optimization

Polyplus transfection

Alengo Nyamay'antu, PhD, Scientific Communication Specialist, Polyplus-transfection

To accelerate process development to produce biotherapeutic protein and antibodies, optimized transient protein production is critical. Choosing the right transfection reagent is key to overcome productivity challenges when working with a wide array of therapeutic antibodies to difficult to express proteins. We demonstrate how FectoPRO® transfection reagent is the go-to transfection reagent that combines productivity and flexibility in suspension CHO and HEK-293 cell lines.

10:50 LIVE PANEL DISCUSSION: Overcoming Production Challenges

Moderator: Renate Kunert, PhD, Department of Biotechnology, University of Natural Resources and Life Sciences (BOKU)
Panelists:
Neesha Dedi, PhD, Senior Scientist, Protein Sciences, UCB Pharma
Mike Zhang, PhD, Professor, Biological Systems Engineering, Virginia Polytechnic Institute & State University
Yoshihiko Matsuda, PhD, Principal Researcher, Research Institute for Bioscience Products & Fine Chemicals, Ajinomoto Co., Inc.
Alengo Nyamay'antu, PhD, Scientific Communication Specialist, Polyplus-transfection

11:10 Session Break - View Our Virtual Exhibit Hall

11:10 CO-PRESENTATION: ASK THE EXPERT with SCIEX

Matt Stone, Biologics Workflow Specialist, SCIEX
Mukesh Malik, Sr. Application Scientist, SCIEX

Join SCIEX analytical technology experts Matthew Stone and Mukesh Malik during an interactive Q&A session to discuss analytical development and optimization of capillary electrophoresis and liquid chromatography-mass spectrometry based methods for protein characterization and quantification. Exciting topics covered include mAbs and mAb variants, cell and gene therapy, vaccines and more!

YOUNG SCIENTIST KEYNOTE

11:25 Young Scientist Keynote Introduction

Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute

11:30 KEYNOTE PRESENTATION: Cryo-Electron Microscopy Structures of Spike Glycoproteins Suggest Pan-Coronavirus Antiviral Strategy

Christine Toelzer, Research Associate, University of Bristol, United Kingdom

We research antivirals to combat present and future coronavirus pandemics. We discovered linoleic acid bound to a hydrophobic pocket in the Cryo-EM structure of the SARS-CoV-2 Spike glycoprotein. Ligand binding locked the protein in a compact closed conformation. Conservation of key AA residues suggested a similar pocket exists in other pathogenic coronaviruses.

12:00 pm Live: Q&A with Young Scientist Keynote

Moderator: Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute
Panelists:
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

12:10 Session Break - View Our Virtual Exhibit Hall

1:00 Close of Difficult-to-Express Proteins Conference

OPTIMIZING PROTEIN EXPRESSION

Enhancing Expression Systems

WEDNESDAY, MAY 12

YOUNG SCIENTIST KEYNOTE

11:25 am Young Scientist Keynote Introduction
Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute

11:30 KEYNOTE PRESENTATION: Cryo-Electron Microscopy Structures of Spike Glycoproteins Suggest Pan-Coronavirus Antiviral Strategy
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

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12:00 pm Live: Q&A with Young Scientist Keynote
Moderator: Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute
Panelists:
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

12:10 Session Break - View Our Virtual Exhibit Hall

IMPROVING EXPRESSION – PLATFORMS

1:10 KEYNOTE PRESENTATION: Engineering Proteins and Hosts Together to Make Biologics
J. Christopher Love, PhD, Professor, Chemical Engineering, Massachusetts Institute of Technology

Proteins are critical for products from biologic medicines to foods to diagnostics. Advances in genome sequencing and gene editing technologies make it possible now to engineer both molecules and hosts to make holistic solutions for production. An integrated approach to modify sequences and host genomes will be presented with examples in vaccines, including candidates for COVID-19, where low costs and high volume production are essential for global health.

1:30 Design Faults and Solutions in Expression Plasmids
Daniel Daley, Assistant Professor, Biochemistry & Biophysics, Stockholm University

In recent work we have identified design faults in commonly used bacterial expression plasmids. We have used modern methods for DNA assembly and directed evolution to correct these design faults. The new designs are a simple and effective way to increase protein production yields in bacterial cell factories.

1:50 Key Learnings and Approaches for Establishing a High-Throughput, Multi-Host Protein Expression Testing and Purification Platform
Edward Kraft, PhD, Senior Scientific Manager, BioMolecular Resources, Genentech

The increasing demands for protein reagents needed for drug discovery efforts drive the development of an efficient methodology for recombinant protein production. Within the BioMolecular Resources Department at Genentech, we have developed a platform for high-throughput construct generation and expression screening in baculovirus, *E. coli* and mammalian transient systems applicable to all protein types and localizations.

2:10 Chemically Defined, High-Density Insect Cell-Based Expression System for Scalable AAV Vector Production
Yasuhiro Ikeda, PhD, Director, Cell Therapeutics, AstraZeneca

The recombinant adeno-associated virus (AAV) vector has emerged as a promising gene therapy platform due to its robust, sustained, and tissue-targeted gene delivery. One major hurdle for clinical AAV application is large-scale manufacturing. Here we present a scalable AAV vector production method using chemically defined, high-density insect cell-based expression system.

2:30 Cell Line Development: Avoiding License, Royalty and Milestone Fees polpharma biologics
Louis Boon, Dr, Chief Scientific Officer, Utrecht, Polpharma Biologics

This presentation shows how to simplify the drug development route to the clinic, without compromising on deliverables, ensuring fast timelines and high titers ahead of industry standards.

- How to avoid royalties, milestones and licence fees during cell line development
- How utilizing ultra-high throughput productivity and scalability assessment ensures high titers can be achieved on a fast timeline
- Why using a CHO-K1 cell line ensures better stability, protein folding and processing

2:50 Holistic Approaches to Rapid Bioprocess Development FUJIFILM Diosynth Biotechnologies
Christopher Lennon, Subject Matter Expert (Molecular & Microbiology), FUJIFILM Diosynth Biotechnologies

Strain selection is a critical step which often gets locked down at an early point during microbial process development, with an emphasis on product titer. However, this is accompanied by a certain amount of risk if product quality is not sufficiently evaluated. A new platform approach to accelerated strain selection, based on both product titer and quality evaluation, leveraging high through put tools and robotics, will be presented.

3:20 LIVE PANEL DISCUSSION: Improving Expression – Platforms
Moderator: J. Christopher Love, PhD, Professor, Chemical Engineering, Massachusetts Institute of Technology
Panelists:
Daniel Daley, Assistant Professor, Biochemistry & Biophysics, Stockholm University
Yasuhiro Ikeda, PhD, Director, Cell Therapeutics, AstraZeneca
Edward Kraft, PhD, Senior Scientific Manager, BioMolecular Resources, Genentech
Louis Boon, Dr, Chief Scientific Officer, Utrecht, Polpharma Biologics
Christopher Lennon, Subject Matter Expert (Molecular & Microbiology), FUJIFILM Diosynth Biotechnologies

3:30 SC3: Developability of Bispecific Antibodies: Formats and Applications
Separate registration required. See short course page for details.

3:40 PEGS Connects - View Our Virtual Exhibit Hall

4:00 Close of Day

THURSDAY, MAY 13

IMPROVING YIELD – CHO CELL LINE ENGINEERING & DEVELOPMENT

9:20 am Model Protein mRNA Transfection in CHO Cells Reveals Production Bottlenecks
Nina Bydlinski, PhD, Austrian Centre of Industrial Biotechnology GmbH

Transfections of large amounts of mRNA can be used to assess compatibility of cell line and recombinant protein while mimicking high productivity, circumventing the need to establish high producing clones early on in product development. By gradually increasing Epo-Fc

mRNA load in CHO cells, bottlenecks in N-glycosylation were detected. Furthermore, we report how this system could verify optimization of N-glycan processing capacities by modulating the expression of key glycosyltransferases.

9:40 Multi-Omic Analysis of Induced Biotherapeutic Protein Production in CHO Cells Reveals Substantial Shifts in Energy Allocation

Gabriel Stancu, PhD, Postdoctoral Fellow, Just Evotech Biologics

Using a tetracycline-inducible expression system (Tet-On) we show that expression of recombinant antibodies in CHO cells is proportional to their mRNA level. In these cells, induction leads to a systematic and extensive reprogramming of the transcriptome, shifting the total expression of constitutive CHO genes towards the production and secretion of the desired antibody. This multi-omic study provides insight into the impact of biotherapeutics production on CHO cell physiology.

10:00 Engineering of Chinese Hamster Ovary Cell Lipid Metabolism Results in an Expanded ER and Enhanced Recombinant Biotherapeutic Protein Production

James D. Budge, PhD, Postdoctoral Fellow, University of Kent

Lipid metabolism plays a key role in cellular processes central to achieving high recombinant protein titres. Processes such as secretion, cell division and endoplasmic reticulum size and function are highly dependent on lipids and their metabolism. We have used genetic engineering to manipulate lipid metabolism in CHO cells, targeting SCD1 and SREBF1 expression, to expand the endoplasmic reticulum and ultimately enhance secretory recombinant protein titres between 1.5 and 9-fold.

10:20 Novel Solution For High Throughput Antibody And Protein Purification Using Magnetic Bead

Bowu Luan, Dr., Product Manager I, Reagent Services, GenScript

Protein purification using traditional chromatography is limited by throughput and requires time-consuming, labor-intensive sample preparation processes. Magnetic beads-based purification permits the incubation of the beads directly into cell culture or crude lysates regardless of sample volume. This provides a simplified approach to direct target capture while reducing sample preparation steps and potentially improving purification quality. The tools and their application to simplify protein purification and screening cost-effectively will be described.

10:50 LIVE PANEL DISCUSSION: Improving Yield – CHO Cell Line Development & Engineering

Moderator: Bjørn Voldborg MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark
Panelists:
James D. Budge, PhD, Postdoctoral Fellow, University of Kent
Nina Bydlinski, PhD, Austrian Centre of Industrial Biotechnology GmbH
Bowu Luan, Dr., Product Manager I, Reagent Services, GenScript
Gabriel Stancu, PhD, Postdoctoral Fellow, Just Evotech Biologics

11:10 Session Break - View Our Virtual Exhibit Hall

LIVE PLENARY PANEL

11:30 Live Plenary Panel: Antibody and Vaccine Development for COVID-19




Moderator: Erica Ollmann Saphire, PhD, Professor, La Jolla Institute for Immunology

- What didn't go well during the pandemic?
- What is the future? Will there be an mRNA vaccine for influenza?
- What did we learn about our country's ability to manufacture during surge production?
- What is needed in terms of infrastructure?

Panelists:
Peter Hotez, MD, PhD, FASTMH, FAAP, Dean, National School of Tropical Medicine; Professor, Departments of Pediatrics, Molecular Virology & Microbiology; Co-Head, Section of Pediatric Tropical Medicine; Health Policy Scholar, Baylor College of Medicine
Lakshmi Krishnan, PhD, A/Vice-President, Life Sciences, National Research Council Canada, Government of Canada
Peter W. Marks, MD, PhD, Director, FDA CBER

12:15 pm Session Break - View Our Virtual Exhibit Hall

BREAKOUT DISCUSSIONS

12:30 Problem Solving Discussions

Join your colleagues and fellow delegates for a focused, informal discussion moderated by a member of our speaking faculty. A small group format allows participants to meet potential collaborators, share examples from their own work and discuss ideas with peers. See website for a full list of topics.

CO-PRESENTATION: TABLE: Common Issues with Transient Protein Production

Richard Altman, Field Application Scientist, Life Science Solutions, Thermo Fisher Scientific
Henry C. Chiou, PhD, Director, Cell Biology, Life Science Solutions, Thermo Fisher Scientific
Dominic Esposito, PhD, Director, Protein Sciences, Frederick National Laboratory

- What are the current challenges to transient protein production?
- What are the keys to optimizing expression?
- How do we optimize the whole protein expression process?
- How can we maintain volumetric yields while scaling transient expression up or down?
- What cell line(s) should we use and when?
- What parameters can impact the quality or physical attributes of transiently produced proteins?

1:10 Session Break - View Our Virtual Exhibit Hall

IMPROVING EFFICACY – POST-TRANSLATIONAL MODIFICATIONS

1:20 FEATURED PRESENTATION: Tailormade Glycans for Improved Therapeutic Proteins

Bjørn Voldborg MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark

I will present a panel of CHO cells able to produce proteins with specific designed glycoprofiles. We have used these cells to produce therapeutic proteins with tailormade glycoprofiles. This approach will be used to produce glycovariants of therapeutic proteins, with better biological properties, such as increased half life, improved activity, etc.

1:40 Protein Expression and Post-Translational Modifications of SARS-CoV-2 Nucleocapsid Protein

Parastoo Azadi, Technical Director & Senior Research Scientist, Analytical Services, University of Georgia

Nucleocapsid protein (N protein) is the most abundant protein in SARS-CoV-2, its sequence is highly conserved, and thus is a potential target for both vaccine development, as well as point-of-care diagnostics. We have performed comprehensive proteomics experiments on two N protein preparations, both expressed in HEK293 cells. Our results show completely different post-translational modifications on the two N protein preparations.

2:00 Rapid High-Yield Expression and Purification of a Fully Post-Translationally Modified and Functional Chaperone (Clusterin)

Mark R. Wilson, PhD, Senior Professor, School of Chemistry and Molecular Bioscience, Molecular Horizons, University of Wollongong

The extensive post-translational processing of clusterin, coupled with its potent binding to any misfolded protein, have meant that its expression as a fully functional recombinant protein has been very difficult and this has limited structure-function studies. We developed a new rapid mammalian cell expression/purification system to accomplish this which has a yield of the order of 30-40 mg per litre of culture and can be completed in about one week.

2:20 High-Yield Expression and Purification of Recombinant Influenza Virus Proteins from Stably-Transfected Mammalian Cell Lines

Giuseppe Andrea Sautto, PhD, Assistant Research Scientist, Center for Vaccines and Immunology, University of Georgia

Influenza viruses infect millions of people each year, resulting in significant morbidity and mortality in the human population. Herein, we

describe the approach for developing stable transfected human cell lines for the expression of recombinant influenza virus hemagglutinin (HA) and recombinant influenza virus neuraminidase (NA) proteins for the purpose of *in vitro* and *in vivo* vaccine development. Our platform can be easily adapted for the production of other pathogen-related proteins.

2:40 Accelerated High-performing, Scalable Monoclonal Antibody Production Based On Samsung Biologics Platform Process

SAMSUNG BIOLOGICS

Sojeong Lee, PhD, Associate Director, USP Group, Samsung Biologics

Selecting the right CDMO partner is critical for any institution as the decision can impact product quality, cost and timeline.

This presentation will delve into the CDO Upstream Process at Samsung Biologics which helps customers achieve high quality products with accelerated timelines.

3:10 LIVE PANEL DISCUSSION: Improving Efficacy – Post-Translational Modifications

Moderator: Parastoo Azadi, Technical Director & Senior Research Scientist, Analytical Services, University of Georgia

Panelists:

Giuseppe Andrea Sautto, PhD, Assistant Research Scientist, Center for Vaccines and Immunology, University of Georgia

Sojeong Lee, PhD, Associate Director, USP Group, Samsung Biologics

Bjørn Voldborg MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark

Mark R. Wilson, PhD, Senior Professor, School of Chemistry and Molecular Bioscience, Molecular Horizons, University of Wollongong

3:30 Close of Conference

ANALYTICAL STREAM

Best Practices and Solutions for Analytical Characterization of Novel Biologics and Emerging Biophysical Methods

The PEGS Analytical Stream focuses on the application of characterization tools to help gain a detailed knowledge of proteins from discovery through development stages. The stream offers comprehensive, individual programs focused on novel therapeutic modalities and biophysical methods, with a mix of case study presentations from large and small biotechs and foundation science from leading academics. For 2021, the program reflects new learnings from COVID-19 rapid discovery/development programs and the increased attention to vaccine and RNA/mRNA therapeutics.

2021
ANALYTICAL STREAM
CONFERENCES

May 11-12

Characterization for Novel Biotherapeutics

AGENDA

May 12-13

Biophysical Methods

AGENDA

PEGSBOSTON
CONFERENCE STREAMS

- ENGINEERING
- ONCOLOGY
- BISPECIFIC ANTIBODIES
- IMMUNOTHERAPY
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REGISTER EARLY & SAVE!

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MAY 11-12, 2021 | 11th Annual

CHARACTERIZATION FOR NOVEL BIOTHERAPEUTICS

Exploring the Analytical Challenges of Emerging Modalities

TUESDAY, MAY 11

9:00 am KEYNOTE PRESENTATION: Lessons Learned from the Pandemic: Development through Production

Anthony R. Mire-Sluis, PhD, Head, Global Quality, AstraZeneca Biologics

During the pandemic, there had to be focus in several areas. Primarily the safety of the workforce and allowing front line operators to function unhindered. Management needed to change its ways of working, prioritize and create the environment for optimal working. Decision-making and digital tools were implemented and an altered culture was created. Ways of dealing with virtual inspections were also developed.

ANTIBODY-DRUG CONJUGATES AND FUSION PROTEINS

9:20 A Rapid Cell-Free Glycoprotein Synthesis Platform for Characterizing SARS-CoV-2 Neutralizing Antibodies

Michael Jewett, PhD, Professor, Chemical and Biological Engineering, Northwestern University

Cell-free biology is the activation of complex biological processes without using intact living cells. While used for more than 50 years across the life sciences as a foundational research tool, a recent technical renaissance has made possible high-yielding cell-free gene expression systems (>g protein/L), including those for glycoprotein synthesis and on-demand biomanufacturing. Here we describe a rapid cell-free glycoprotein synthesis platform for characterizing SARS-CoV-2 neutralizing antibodies.

9:40 State-of-the-Art Mass Spectrometry Methods for Characterizing mAbs, ADCs, BsAbs and Fc-fusion Proteins

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

Developability and comparability assessment of current and next generation of biologics such as engineered mAbs, Fc-fusion proteins, BsAbs and 3G-ADCs requires state-of-the-art analytical and structural methods. Case studies will be presented based on native and ion mobility MS, Collision Induced Unfolding (CIU), multiplexed Top and Middle-Down MS, multiple fragmentation techniques, comprising high energy collisional-, electron-transfer and UV photo-dissociation (HCD, ETD and UVPD), CE-MS and quantification of trace-level HCPs by MS.

10:00 Integrated Analytical Strategies for Attributes Characterization of ADCs and Fusion Proteins

Guodong Chen, PhD, Scientific Director, Bristol Myers Squibb

Since the introduction of the first recombinant DNA-derived insulin, biotherapeutics market has shown steady growth. Novel modalities such as ADCs and fusion proteins have received increasing attention in the pharmaceutical industry as targeted therapies. Integrated analytical strategies are required to address issues in attributes characterization. This presentation will discuss recent developments in protein analytics for elucidating key attributes, including phase-appropriate characterization strategy, integrated/orthogonal methodology and case studies.

10:20 Bruker - The Next Generation of SPR instruments: Introduction to the SPR-Pro series

Hniang Khamh, Ph.D., Applications Scientist for Surface Plasmon Resonance (SPR), Bruker

In the summer of 2020, Bruker launched its next generation of SPR instruments, the "Pro series". The "Pro series" instruments are available with either 32 sensor spots (8x4 array) or 24 sensor spots (8x3 array). The instruments are respectively named the SPR-32 Pro and the SPR-24 Pro. These instruments have outstanding sensitivity, fast cycle time with individual needle control capability and can run fully automated with an external robot.

10:50 LIVE PANEL DISCUSSION: Antibody-Drug Conjugates and Fusion Proteins: Fc-Competent or Fc-Silent?

Moderator: Alain Beck, PhD, Senior Director, Biologics CMC and Developability, Pierre Fabre, France
Panelists:
Guodong Chen, PhD, Scientific Director, Bristol Myers Squibb
Michael Jewett, PhD, Professor, Chemical and Biological Engineering, Northwestern University
Anthony R. Mire-Sluis, PhD, Head, Global Quality, AstraZeneca Biologics
Chris Heger, Ph.D., Director Applications Science, Applications Science, ProteinSimple, a Bio-Techne brand
Hniang Khamh, Ph.D., Applications Scientist for Surface Plasmon Resonance (SPR), Bruker

11:10 Session Break - View Our Virtual Exhibit Hall

11:10 ASK THE EXPERT with Svar Life Science

Michael G. Tovey, Ph.D, Chief Scientific Advisor of Svar Life Science France, Svar Life Science

Svar´s Expert session will focus on AAV mediated gene therapy and potential neutralizing antibody response to AAV vectors. We know the importance of precisely quantify both the neutralizing antibody response prior to treatment, and the neutralizing antibody response to the recombinant AAV vector following treatment. Talk to us about how our highly sensitive reporter-gene assays are used for the quantification of NAbs to recombinant AAV vectors with different capsid specificities.

PLENARY KEYNOTE ADDRESS

11:25 Plenary Keynote Introduction

Jennifer R. Cochran, PhD, Shriram Chair & Professor, Bioengineering & Chemical Engineering, Stanford University

11:30 KEYNOTE PRESENTATION: The Coming of Age of *de Novo* Protein Design

David A. Baker, PhD, Henrietta & Aubrey David Endowed Professor, Biochemistry, University of Washington

I will describe the *de novo* design of fluorescent proteins, membrane penetrating macrocycles, transmembrane protein channels, allosteric proteins that carry out logic operations, and self-assembling nanomaterials and polyhedra. I will also discuss the application of these methods to COVID-19 challenges.

12:00 pm LIVE: Q&A with Audience

Moderator: Jennifer R. Cochran, PhD, Shriram Chair & Professor, Bioengineering & Chemical Engineering, Stanford University
Panelists:
David A. Baker, PhD, Henrietta & Aubrey David Endowed Professor, Biochemistry, University of Washington

12:10 Session Break - View Our Virtual Exhibit Hall

BREAKOUT DISCUSSIONS

12:20 Problem Solving Discussions

Join your colleagues and fellow delegates for a focused, informal discussion moderated by a member of our speaking faculty. A small group format allows participants to meet potential collaborators, share examples from their own work and discuss ideas with peers. See website for a full list of topics.

TABLE: Analytical Method Development for Emerging Biotherapeutic Modalities

Yi Wen, PhD, Research Scientist, Lilly Research Laboratories, Eli Lilly & Co.

1:00 Session Break - View Our Virtual Exhibit Hall

BI-SPECIFIC AND MULTI-SPECIFIC ANTIBODIES

1:10 Characterization of Multiclonics® Antibodies Based on Natural IgG: Developability, Manufacturing and Behavior in Patients

Franziska Mortensen, PhD, Scientist, Merus N.V., Netherlands

Many heavily engineered multispecific antibody formats have been generated and are analyzed in preclinical and clinical studies. As designed these molecules often encounter challenges during discovery, manufacturing and finally in patients. We employed the natural IgG format with minimal engineering to generate common light chain bi- and trispecific antibodies (Multiclonics®) with optimal biophysical and pharmacokinetic properties. The discovery, developability and in-patient behavior of our multispecific molecules will be discussed.

1:30 A Biological Rationale for Toxicity Mitigation with CD3 Bispecifics

Teemu T. Junttila, PhD, Principal Scientist, Translational Oncology, Genentech

Early clinical data with CD3 bispecific antibodies has demonstrated transformational anti-tumor activity. Systemic cytokine release and on-target/off-tumor toxicity are the main adverse effects limiting the clinical utility of CD3 bispecific. Our data describe the cellular and molecular mechanism of CD3 bispecific-induced cytokine release and demonstrate that T cell killing activity is completely disconnected from the cytokine release providing a strong rationale for intervention by blocking various pyrogens without compromising efficacy.

1:50 Empty/Full AAV Characterization by Orthogonal Approaches

Santoshkumar L. Khatwani, PhD, Associate Director, Analytical Development, Sangamo Therapeutics

The empty capsids are product-related impurities present in the rAAV products. It is important to quantify the full, empty and partial capsids in a rAAV product. This presentation will focus on different methods that are used for empty/full AAV characterization. In addition, orthogonal approaches will be discussed.

2:10 Method Crossovers from Proteins to Cell and Gene Therapies

Thomas F. Lerch, PhD, Senior Principal Scientist, Analytical R&D, Pfizer Inc.

New biotherapeutic modalities, such as AAV gene therapy vectors, show significant promise in the clinic. As such, accelerated clinical development is common, requiring rapid analytical method implementation. Extensive protein therapeutic development experience can be leveraged to establish new modality product testing and characterization strategies. This talk will focus on crossing over from protein and antibody analytics to an informed and meaningful analytical test strategy for gene therapy vectors.

2:30 Gene Therapy Products: is Viral Clearance needed? What do the guidelines require?

charles river

Tareq Jaber, PhD, Sr.Manager of Process Evaluation, Charles River

3:00 LIVE PANEL DISCUSSION: Characterization Challenges for Novel Modalities

Moderator: Santoshkumar L. Khatwani, PhD, Associate Director, Analytical Development, Sangamo Therapeutics

Panelists:

Teemu T. Junttila, PhD, Principal Scientist, Translational Oncology, Genentech

Thomas F. Lerch, PhD, Senior Principal Scientist, Analytical R&D, Pfizer Inc.

Tareq Jaber, PhD, Sr.Manager of Process Evaluation, Charles River

3:20 PEGS Connects - View Our Virtual Exhibit Hall

4:00 Close of Day One

3:30 SC1: CAR T Cell Therapy from A-Z SC2: Introduction to Gene Therapy Products Manufacturing and Analytics

Separate registration required. See short course page for details.

WEDNESDAY, MAY 12

CHARACTERIZATION FOR CHALLENGING TARGETS AND MOLECULES

9:00 am Dynamic Mass Redistribution (DMR) Assay for GPCR Characterization

Lisa A. Stott, PhD, Senior Scientist I, Sosei Heptares

A common problem in drug discovery is a lack of clinical translation from recombinant screening systems. This is particularly true for chemokine receptors, where ligand/receptor redundancy provides an additional challenge; CXCR2 antagonist activity is not fully predicted by recombinant systems. We describe neutrophil dynamic mass redistribution assays which are sufficiently reliable for medium-throughput screening using endogenous receptors and demonstrate better correlation with the clinical target engagement assay, CD11b upregulation.

9:20 The Generation of Synthetic Nanobodies as Modulators of Ion Channel Function

Raimund Dutzler, Professor, Biochemistry, University of Zurich, Switzerland

In mammals, the members of the LRRC8 family of integral membrane proteins form heteromeric ion channels, which open an anion-selective pore in response to osmotic swelling. We have selected nanobodies from synthetic libraries to target the cytosolic domains of the obligatory channel subunit LRRC8A. These nanobodies are specific, recognize different epitopes and exhibit distinct functional properties with some acting as allosteric inhibitors and others as potentiators of ion channel function.

9:40 Challenges with the Functional Characterization of Ion Channel Targeting Peptides and Antibodies

Heike Wulff, PhD, Professor, Pharmacology, School of Medicine, University of California, Davis

Ion channels constitute attractive drug targets for neurological diseases, pain and immunomodulation. However, achieving selectivity with small molecule drugs has been challenging and there currently is a growing trend to target ion channels with biologics such as peptides and antibodies. Using Nav1.7 targeting peptides and Kv1.3 targeting antibodies as examples, I will describe the challenges involved in screening and characterizing ion channel targeting biologics using binding assays and electrophysiology.

10:00 An Automated and Unbiased Peptide Mapping Approach for Site-Specific Glycosylation Fingerprinting of Highly Glycosylated Proteins

Dhanashri Bagal, PhD, Senior Scientist, Discovery Attribute Sciences, Amgen

Protein glycosylation is a critical attribute of recombinantly produced proteins and can affect structure and function. Capturing site-specific glycan heterogeneity for highly glycosylated proteins can be challenging. Here we present a rapid peptide mapping approach that provides a glyco-fingerprint to each glycosylation site thus allowing us to compare lots of the proteins produced under various conditions. Although semi-quantitative, this fingerprinting can be useful to monitor lot-to-lot variability.

10:20 Rapid screening and epitope binning of anti-SARS-CoV-2 antibodies from a naïve phage library

SARTORIUS

Matthew R. Chang, MS, Research Scientist, Cancer Immunology and Virology, Dana-Farber Cancer Institute

At the beginning of 2020, SARS-CoV-2 presented a serious global threat and no therapies existed to slow the spread of infections around the world. As our part of this effort to develop effective therapies, the Marasco Lab used its 27-billion-member naïve phage library to perform parallel SARS-CoV-2 S1 and RBD panning campaigns and were able to rapidly isolate a large panel of anti-SARS-CoV-2 spike antibodies. Utilizing the Octet RED96 platform, we performed high throughput kinetic screening to quickly eliminate sub-par antibodies. Subsequent competitive binding assays with CR3022 and soluble ACE2 allowed for broad epitope binning and identification of antibodies that blocked the ACE2-RBD interface. These ACE2 blocking antibodies were prioritized for further characterization, including fine resolution epitope binning within the group and viral neutralization assays. With the emergence of variant strains of SARS-CoV-2, further studies have investigated the effect of these spike mutations on antibody binding. The Octet RED96 system was critical in our efforts to identify potently neutralizing antibodies, allowing us to rapidly screen a large panel of unknown antibodies to identify lead candidates for characterization and development.

10:50 LIVE PANEL DISCUSSION: Characterization for Challenging Molecules

Moderator: Dhanashri Bagal, PhD, Senior Scientist, Discovery Attribute Sciences, Amgen
Panelists:
Raimund Dutzler, Professor, Biochemistry, University of Zurich, Switzerland
Lisa A. Stott, PhD, Senior Scientist I, Sosei Heptares
Heike Wulff, PhD, Professor, Pharmacology, School of Medicine, University of California, Davis
Matthew R. Chang, MS, Research Scientist, Cancer Immunology and Virology, Dana-Farber Cancer Institute

11:10 Session Break - View Our Virtual Exhibit Hall

11:10 CO-PRESENTATION: ASK THE EXPERT with SCIEX

Matt Stone, Biologics Workflow Specialist, SCIEX
Mukesh Malik, Sr. Application Scientist, SCIEX

Join SCIEX analytical technology experts Matthew Stone and Mukesh Malik during an interactive Q&A session to discuss analytical development and optimization of capillary electrophoresis and liquid chromatography-mass spectrometry based methods for protein characterization and quantification. Exciting topics covered include mAbs and mAb variants, cell and gene therapy, vaccines and more!

YOUNG SCIENTIST KEYNOTE

11:25 Young Scientist Keynote Introduction

Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute

11:30 KEYNOTE PRESENTATION: Cryo-Electron Microscopy Structures of Spike Glycoproteins Suggest Pan-Coronavirus Antiviral Strategy

Christine Toelzer, Research Associate, University of Bristol, United Kingdom

We research antivirals to combat present and future coronavirus pandemics. We discovered linoleic acid bound to a hydrophobic pocket in the Cryo-EM structure of the SARS-CoV-2 Spike glycoprotein. Ligand binding locked the protein in a compact closed conformation. Conservation of key AA residues suggested a similar pocket exists in other pathogenic coronaviruses.

12:00 pm Live: Q&A with Young Scientist Keynote

Moderator: Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute
Panelists:
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

12:10 Session Break - View Our Virtual Exhibit Hall

1:00 Close of Characterization for Novel Biotherapeutics Conference

MAY 12-13, 2021 | 9th Annual

BIOPHYSICAL METHODS

Characterizing and Optimizing the Physical Properties of Next Generation Biologics

WEDNESDAY, MAY 12

YOUNG SCIENTIST KEYNOTE

11:25 am Young Scientist Keynote Introduction
Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute

11:30 KEYNOTE PRESENTATION: Cryo-Electron Microscopy Structures of Spike Glycoproteins Suggest Pan-Coronavirus Antiviral Strategy
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

We research antivirals to combat present and future coronavirus pandemics. We discovered linoleic acid bound to a hydrophobic pocket in the Cryo-EM structure of the SARS-CoV-2 Spike glycoprotein. Ligand binding locked the protein in a compact closed conformation. Conservation of key AA residues suggested a similar pocket exists in other pathogenic coronaviruses.

12:00 pm Live: Q&A with Young Scientist Keynote
Moderator: Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute
Panelists:
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

12:10 Session Break - View Our Virtual Exhibit Hall

ACCELERATING DISCOVERY STAGE CHARACTERIZATION STUDIES

1:10 Characterization Studies during Rapid R&D for COVID-19 Vaccines and Treatments
Bryan Faust, Graduate Researcher, Biophysics, University of California, San Francisco

Enabled by recent structural and biophysical analyses, researchers have rapidly developed and characterized novel therapeutic and prophylactic approaches for COVID-19 treatment. In this talk, I will highlight our recent work to identify and further engineer single-domain antibodies (nanobodies) capable of SARS-CoV-2 neutralization. Using kinetic analyses and structure-guided design, we show how nanobody multimerization yields exceptional neutralization potency through conformational "control" of the viral Spike protein.

1:30 FEATURED PRESENTATION: New Methods for Biotherapeutic Developability Analysis
Benjamin J. Hackel, PhD, Associate Professor, Chemical Engineering & Materials Science, University of Minnesota

Protein developability challenges hinder the discovery and engineering pipeline. We present three high-throughput genotype-phenotype linked assays that measure developability proxies for 105 variants (with efficient scalability to 107). A random forest model trained on the assay data predicted recombinant expression of scaffold variants with 5x greater efficiency and 35% increased accuracy than a sequence-derived model. These assays enable developable protein discovery, inform protein design, and allow more precise landscape visualization.

NEW APPLICATIONS FOR MASS SPECTROMETRY

1:50 Denaturing and Native-MS in Biopharmaceutical Research: A Historical to Present Day Perspective
Iain Campuzano, PhD, FRSC, Senior Principal Scientist, Discovery Attribute Sciences, Amgen

The origins of LC-MS can be traced back to 1968 where direct liquid introduction from a capillary into a high vacuum electron impact source of an MS instrument was implemented. Now mass spectrometry plays a pivotal role throughout all stages of drug development and is now as ubiquitous as other analytical techniques such as SPR and NMR. Native-MS is evolving into a highly enabling analytical technique within biopharma.

2:10 Combined HDX, MD and Docking Approaches to Understand Excipient Interactions
Paul Dalby, PhD, Professor, Biochemical Engineering, University College London

Protein stability is critical for the successful development of non-aggregating biopharmaceuticals. We have combined biophysical analyses, protein engineering, formulation screening, and molecular modelling, to characterise factors that influence protein aggregation. Examples will be presented from small-angle X-ray scattering, hydrogen-deuterium exchange mass spectrometry, and molecular dynamics simulations. Insights are being used to develop improved protein engineering and formulation design strategies for the minimisation of aggregation in liquid and freeze-dried forms.

2:30 High throughput characterization of antibody, AAV and cell therapy aggregates using the Aura

halo labs

Bernardo Cordovez, PhD, Chief Science Officer and Founder, Halo Labs

In all biological products, distinguishing aggregated API from other particle types matters for understanding the root cause of instability. Until now, subvisible particle characterization methods have been unreliable, slow, and difficult to use across many workflows. Introducing the Aura, a 96-well, low-volume, high throughput aggregate and particle imaging system can rapidly size, count, and characterize biological particles and identify them as proteins, non-proteins, cellular aggregates, or other types of molecules.

2:50 Session Break - View Our Virtual Exhibit Hall

3:00 LIVE PANEL DISCUSSION: New Applications for Mass Spectrometry
Moderator: Iain Campuzano, PhD, FRSC, Senior Principal Scientist, Discovery Attribute Sciences, Amgen
Panelists:
Paul Dalby, PhD, Professor, Biochemical Engineering, University College London
Bryan Faust, Graduate Researcher, Biophysics, University of California, San Francisco
Benjamin J. Hackel, PhD, Associate Professor, Chemical Engineering & Materials Science, University of Minnesota
Bernardo Cordovez, PhD, Chief Science Officer and Founder, Halo Labs

3:20 PEGS Connects - View Our Virtual Exhibit Hall

3:30 SC3: Developability of Bispecific Antibodies: Formats and Applications
Separate registration required. See short course page for details.

4:00 Close of Day

THURSDAY, MAY 13

DETECTION AND CHARACTERIZATION OF AGGREGATION

9:00 am Developing Industry-Relevant Protein Aggregate Samples for Biopharmaceutical Analytical Methods

Christopher J. Roberts, PhD, Professor, Chemical & Biomolecular Engineering, University of Delaware

There is an evolving pre-competitive effort to develop protein aggregates that are relevant for the biopharmaceutical industry, from both an early-stage and later-stage perspective. This builds from industry consortia and workshop efforts through the Biomolecular Interaction Technologies Center (BITC) and associated partners (to be named). The talk will focus on priorities for current efforts with technology providers and instrument developers, and building a broader community effort in this area.

9:20 Cellular Models to Evaluate the Impact of Therapeutic Antibody Aggregates on Immunogenicity

Isabelle Turbica, PhD, Assistant Professor, Biotechnology, School of Pharmacy, Paris-Saclay University, France

Aggregation is a concern especially during the reconstitution and administration of therapeutic antibody (TAb) preparations, as it seems to be correlated with anti-drug antibodies (ADA) development in treated patients. This talk will deal with the optimization of separative methods for TAb aggregates detection and characterization, and will then focus on *in vitro* cell-based assays, to evaluate the potential of aggregated TAbs to induce immune responses that could drive ADA development.

MODELING AND MACHINE LEARNING

9:40 Pareto Optimal Antibody Engineering Guided by Machine Learning Methods

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

We have developed machine learning methods for identifying lead antibodies and affinity-matured variants with Pareto optimal combinations of affinity and biophysical properties. Our approach combines novel descriptors of antibody molecular features with neural networks to identify antibody variants with different levels of affinity improvement while compromising other key properties (e.g., specificity) by the least amount possible. These methods reduce the required experimentation needed to co-optimize antibody affinity and biophysical properties.

10:00 Antibody Repertoire Modeling & Mutational Profiling Reveal Biophysical Selection Motifs

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

Despite many years of study, the characteristics of effective antibody selection remain incompletely understood. Here we performed large-scale analyses of antibody improvement pathways to explore antibody developmental features. We also mined human antibody repertoire sequences and revealed a functional selection pressure for MHC-II epitope deletion within antibody proteins. These data suggest that HLA-based personalization shapes the composition and durability of human antibody immunity, with important implications for protein therapeutic development.

10:20 Orthogonal method for monitoring Higher Order Structures (HOS) with QCL Mid-IR liquid analyzer

DRS DAYLIGHT SOLUTIONS

Santosh Hodawadekar, PhD, Director, Biopharma Application, Life Sciences, DRS Daylight Solutions

Here we present precision-based high protein titer measurements and secondary structure prediction in real-time using QCL-Mid IR Culpeo liquid analyzer. This unique analytical tool can serve as an orthogonal method for characterizing higher-order structures (HOS) and conduct Forced degradation studies (FDS) at the key unit operations steps by quantifying the changes in the secondary structures of drug substances.

10:50 LIVE PANEL DISCUSSION: Predicting and Controlling Therapeutic Protein CQAs Related to Biophysical Properties and Aggregation

Moderator: Christopher J. Roberts, PhD, Professor, Chemical & Biomolecular Engineering, University of Delaware
Panelists:
Brandon DeKosky, PhD, Assistant Professor, The University of Kansas
Peter M. Tessier, PhD, Albert M. Mattocks Professor, Pharmaceutical Sciences & Chemical Engineering, University of Michigan
Isabelle Turbica, PhD, Assistant Professor, Biotechnology, School of Pharmacy, Paris-Saclay University, France
Santosh Hodawadekar, PhD, Director, Biopharma Application, Life Sciences, DRS Daylight Solutions

11:10 Session Break - View Our Virtual Exhibit Hall

LIVE PLENARY PANEL

11:30 Live Plenary Panel: Antibody and Vaccine Development for COVID-19




Moderator: Erica Ollmann Saphire, PhD, Professor, La Jolla Institute for Immunology

- What didn't go well during the pandemic?
- What is the future? Will there be an mRNA vaccine for influenza?
- What did we learn about our country's ability to manufacture during surge production?
- What is needed in terms of infrastructure?

Panelists:
Peter Hotez, MD, PhD, FASTMH, FAAP, Dean, National School of Tropical Medicine; Professor, Departments of Pediatrics, Molecular Virology & Microbiology; Co-Head, Section of Pediatric Tropical Medicine; Health Policy Scholar, Baylor College of Medicine
Lakshmi Krishnan, PhD, A/Vice-President, Life Sciences, National Research Council Canada, Government of Canada
Peter W. Marks, MD, PhD, Director, FDA CBER

12:15 pm Session Break - View Our Virtual Exhibit Hall

BREAKOUT DISCUSSIONS

12:30 Problem Solving Discussions

Join your colleagues and fellow delegates for a focused, informal discussion moderated by a member of our speaking faculty. A small group format allows participants to meet potential collaborators, share examples from their own work and discuss ideas with peers. See website for a full list of topics.

TABLE: The Role of Denaturing and Native-MS in Biopharmaceutical Research: From mAbs to Membrane Proteins and Beyond

Iain Campuzano, PhD, FRSC, Senior Principal Scientist, Discovery Attribute Sciences, Amgen

1:10 Session Break - View Our Virtual Exhibit Hall

NEW TECHNOLOGIES FOR MINIMIZING SAMPLE CONSUMPTION

1:20 Goodbye to Phage ELISA: Multiplex Flow Cytometry Assay for Phage-Displayed Binders

Shohei Koide, PhD, Professor, Biochemistry & Molecular Pharmacology, New York University School of Medicine; Perlmutter Cancer Center, NYU Langone Health

Phage ELISA has been a workhorse in clone characterization, but it is labor-intensive and consumes large amounts of antigens. We have developed a flow cytometry-based multiplex assay for phage-displayed binders utilizing off-the-shelf reagents. It simultaneously measures binding to five antigens and reduces antigen consumption by >500-fold within shorter experimental time, compared with phage ELISA. This assay accelerates the discovery of clones with desirable specificity profiles early in the development pipeline.

1:40 New Analytical and Biophysical Tools to Minimize Sample Consumption for Release and Characterization Assays of AAV- and Protein-Based Products

George Bou-Assaf, PhD, Scientist, Analytical Development – Product & Technology Development, Biogen

AAV products comprise a protein capsid and a nucleic acid packaged inside. The smaller manufacturing scales of AAV-based products make it particularly challenging to develop methods with very limited sample availability. We describe traditional characterization methods and the challenge of their applicability to AAV-based products. We evaluate new technologies which require minimal sample amounts to inform critical quality attributes and we demonstrate how they are orthogonal to the traditional methods.

PREDICTIVE METHODS

2:00 Intrinsic Physicochemical Profile of Biologic Medicines

Sandeep Kumar, PhD, Senior Research Fellow, Computational Biochemistry and Bioinformatics, Boehringer Ingelheim Pharmaceuticals

We recently collected amino acid sequences of currently marketed antibody-based biologic medicines and used these to derive their homology-based structural models. Availability of both sequence and structural models of these biotherapeutics afforded us an opportunity to analyze their physicochemical attributes from a perspective of developability. These analyses have resulted in a profile that can be used to estimate 'medicine-likeness' of the biologic drug candidates currently in discovery and development.

2:20 The Viscosity of Concentrated Antibody Solutions: What Causes It and How to Predict It

Jeremy Schmit, PhD, Associate Professor, Biochemistry and Molecular Biophysics, Kansas State University

We present a physics-based model to understand the mechanism of antibody viscosity. In this model variable domain interactions lead to the formation of elongated complexes that entangle with each other. A theory accounting for the reptation dynamics of these complexes is able to describe the viscosity as a function of concentration and shear rate. This shows that viscosity can be predicted from measurements of the two-body interaction.

2:40 Characterization of recombinant adeno-associated virus (AAV) using LC and MS technologies

Waters
THE SCIENCE OF WHAT'S POSSIBLE.

Ximo Zhang, Principal Scientist, Biopharma, Waters Corporation

To fully realize the potential of AAV vectors for gene therapy applications, reliable and efficient analytical technologies have become increasingly relevant and urgent to help establish a structure-function relationship, guide the development of manufacturing process, and assess the quality of clinical materials. In this talk, we will highlight the novel LC/MS workflows that are developed for the analysis of recombinant AAV vectors, including aggregation, titer, empty/full ratio, and PTM analysis.

3:00 Session Break - View Our Virtual Exhibit Hall

3:10 LIVE PANEL DISCUSSION: Methods and Technologies for Accelerating Analytical Development

Moderator: George Bou-Assaf, PhD, Scientist, Analytical Development – Product & Technology Development, Biogen
Panelists:
Shohei Koide, PhD, Professor, Biochemistry & Molecular Pharmacology, New York University School of Medicine; Perlmutter Cancer Center, NYU Langone Health
Sandeep Kumar, PhD, Senior Research Fellow, Computational Biochemistry and Bioinformatics, Boehringer Ingelheim Pharmaceuticals
Jeremy Schmit, PhD, Associate Professor, Biochemistry and Molecular Biophysics, Kansas State University
Ximo Zhang, Principal Scientist, Biopharma, Waters Corporation

3:30 Close of Conference

IMMUNOGENICITY STREAM

Ensuring the Safety and Efficacy of Biologics

This year's Immunogenicity Stream focuses on the latest science, technologies and strategies to ensure the safety and efficacy of biologics, with a particular focus on novel modalities including cell & gene therapies, bispecifics, immunotherapies and ADCs. Part One provides a practical, comprehensive introduction to immunogenicity via an interactive training seminar. Part Two examines immunogenicity assessment and management including: assay development and validation, clinical relevance, drug and target interference, risk assessment and recent advances with predictive studies and tools.

2021
IMMUNOGENICITY STREAM
CONFERENCES

May 11-12

Introduction to Immunogenicity

Training SEMINARS By Cambridge Healthtech Institute

AGENDA

May 12-13

Immunogenicity Assessment and Management

AGENDA

PEGS BOSTON
CONFERENCE STREAMS

- ENGINEERING
- ONCOLOGY
- BISPECIFIC ANTIBODIES
- IMMUNOTHERAPY
- EXPRESSION
- ANALYTICAL
- **IMMUNOGENICITY**
- COVID INTERVENTIONS

DAY 1: TUESDAY, MAY 11 - 9:00 AM - 3:30 PM; DAY 2: WEDNESDAY, MAY 12: 9:00 AM - 1:00 PM

INTRODUCTION TO IMMUNOGENICITY

This 1.5-day virtual 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 guidances, followed by assay and bioanalytical assessment strategies for traditional and emerging biologics. Other topics include predictive models and reporting immunogenicity.

Instructors:

Bonnie Rup, PhD, Biotechnology Consultant, Bonnie Rup Consulting

Sofie Pattijn, Founder & CTO, ImmunXperts SA

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.

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genomeweb

MAY 12-13, 2021 | 13th Annual

IMMUNOGENICITY ASSESSMENT AND MANAGEMENT

Clinical Relevance, Assay Development, Risk Assessment and Predictive Studies

WEDNESDAY, MAY 12

YOUNG SCIENTIST KEYNOTE

11:25 am Young Scientist Keynote Introduction
Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute

11:30 KEYNOTE PRESENTATION: Cryo-Electron Microscopy Structures of Spike Glycoproteins Suggest Pan-Coronavirus Antiviral Strategy
Christine Toelzer, Research Associate, University of Bristol, United Kingdom
We research antivirals to combat present and future coronavirus pandemics. We discovered linoleic acid bound to a hydrophobic pocket in the Cryo-EM structure of the SARS-CoV-2 Spike glycoprotein. Ligand binding locked the protein in a compact closed conformation. Conservation of key AA residues suggested a similar pocket exists in other pathogenic coronaviruses.

12:00 pm Live: Q&A with Young Scientist Keynote
Moderator: Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute
Panelists:
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

12:10 Session Break - View Our Virtual Exhibit Hall

CLINICAL RELEVANCE OF ADA

1:10 AAV5 Mediated Gene Therapy for Hemophilia A: Advances with Clinical Immunogenicity Data Related to Valoctocogene Roxaparvovec
Brian Long, PhD, Associate Director, Immunogenicity Assessment, BioMarin Pharmaceutical, Inc.
Understanding immune responses against viral vectors is essential for the development of AAV-based gene therapies. Pre-existing immunity in the form of capsid-specific antibody can neutralize AAV upon dose administration resulting in attenuated therapeutic efficacy. Following administration of valoctocogene roxaparvovec, an AAV5-mediated gene therapy for the treatment of Hemophilia-A, both humoral and cellular responses specific for AAV capsid develop but have not been consistently associated with clinical safety or efficacy parameters.

1:30 Introduction of a Drug-Tolerant ADA Method for Infliximab in Clinical Routine
Anna Fogdell-Hahn, PhD, Associate Professor, Clinical Neuroscience, Karolinska Institute
During drug development, the immunogenicity issue is an essential part, but the introduction of sustainable routines has not been fully implemented in clinical practice. If used optimally, however, measuring drug and anti-drug antibodies (ADA) level have the potential to lead to a more personalized and efficient treatment regime, and enable identification of ADA-positive patients before the underlying disease flares or allergic reactions occur. How, will be discussed in this talk.

ASSAY DEVELOPMENT AND VALIDATION

1:50 The Method History Report: An Adaptable Tool for Communicating Immunogenicity Assay Development and Validation
Kristin Hollister, PhD, Senior Research Scientist, Eli Lilly and Company
Throughout development of a therapeutic protein, the immunogenicity assay validation history can become substantial. This volume of work may confound review of clinical immunogenicity within the Biologics License Application, thus, leading to questions and information requests from regulators. Utilization of a new document, the Method History Report, has streamlined communication of the assay validation history and authoring of the Integrated Summary of Immunogenicity.

2:10 Bioanalytical Strategies For The Development of ADA Assay in Population with Pre-existing Antibodies
Madhukar Aryal, Scientist-1, Amunix Pharmaceuticals
Pegvaliase is an enzyme substitution therapy for Phenylketonuria (PKU). This presentation will discuss the development and validation of a hybrid ligand binding-liquid chromatography/tandem mass spectrometry assay to measure neutralizing antibodies (NAbs) that inhibit pegvaliase enzymatic activity. A subset of clinical trial subjects developed sustained NAbs, but the majority of these subjects achieved efficacy following individualized dose titration.

2:30 Don't let the immune response blind-side you : The importance of early immunogenicity and immunotoxicity assessment Lonza
Noel Smith, PhD, Head of Immunology, Applied Protein Services Cambridge, Lonza
Harnessing the power of the immune system has revolutionised treatment options for patients. However there are concerns about unwanted immune responses leading to serious adverse events. Regulatory agencies require an assessment of a biotherapeutic's potential to trigger these unwanted responses. This presentation will focus on solutions to address the potential for unwanted immune responses and why doing so early in candidate selection can have a very positive impact on development time.

3:00 LIVE PANEL DISCUSSION: Clinical Relevance of ADA and Assay Development and Validation
Moderator: Brian Long, PhD, Associate Director, Immunogenicity Assessment, BioMarin Pharmaceutical, Inc.
Panelists:
Anna Fogdell-Hahn, PhD, Associate Professor, Clinical Neuroscience, Karolinska Institute
Kristin Hollister, PhD, Senior Research Scientist, Eli Lilly and Company
Madhukar Aryal, Scientist-1, Amunix Pharmaceuticals
Noel Smith, PhD, Head of Immunology, Applied Protein Services Cambridge, Lonza

3:20 PEGS Connects - View Our Virtual Exhibit Hall

3:30 SC3: Developability of Bispecific Antibodies: Formats and Applications
Separate registration required. See short course page for details.

4:00 Close of Day

THURSDAY, MAY 13

RECENT ADVANCES WITH NOVEL MODALITIES

9:00 am KEYNOTE PRESENTATION: Evaluation of Antibody Immunity Against Viral Gene Therapy Modalities Using Total Antibody Protocol
Boris Gorovits, PhD, Vice President, In Vitro Pharmacology, Biomarker Discovery and Bioanalysis, Sana Biotechnology
Ability to detect and understand antibody-based immunity against viral gene therapeutics is a critical element in GTx modality development. Humoral (antibody) based anti-GTx immunity has been described by detecting Neutralizing and Total antibodies. Several companies' effort directed to align on the value of detecting Total antibody response and applied analytical methodologies will be reviewed in this presentation.

9:20 Using Integrated Approaches to Characterize Immunogenic Responses Towards Bispecific Antibodies
Kate Peng, PhD, Director/Senior Scientist, BioAnalytical Sciences, Genentech
Bispecific antibodies (bsAbs) are a novel class of antibodies that aim to improve drug efficacy by simultaneously working on two targets. Compared to the conventional monospecific antibody therapeutics,

bsAbs have a relatively shorter development history. This presentation will use two case studies to discuss the benefits of using integrated approaches to characterize immunogenicity findings of bsAbs.

9:40 Assessment of Transgene and AAV Immunogenicity in Gene Therapy

Don Zhong, PhD, Dir Bioanalytical Sciences, Bioanalytical Sciences, Sangamo Therapeutics

Understanding immunogenicity of transgenes and AAV capsids is key to fully deciphering the potential of gene therapy. Pre-existing and treatment-induced immune responses are big hurdles to overcome to ensure safe, durable, efficacious treatment for a range of genetic diseases. This presentation discusses bioanalytical methods for measuring humoral, innate, and adaptive immunity associated with genomic medicines.

MANAGING DRUG AND TARGET INTERFERENCE

10:00 Considerations for Managing Drug and Target Interference in Anti-Drug Antibody Assays

John Kamerud, PhD, Director, Bioanalytical, Pfizer

This talk will discuss the interference by drug and target in assays for the detection of binding (ADA) or neutralizing (Nab) anti-drug antibodies and review approaches that have been employed to eliminate it. Some of the considerations covered include relevant concentrations of ADA, drug and target, affinity of natural ADA versus positive control, effects of acid dissociation and reporting of results generated in the presence of excess drug or target.

10:20 Quantification of the Neutralizing Antibody Response to Recombinant AAV Vectors

Michael G. Tovey, Ph.D, Chief Scientific Advisor of Svar Life Science France, Svar Life Science

Highly sensitive iLite® reporter assay, providing a highly sensitive, rapid, precise method for quantifying NAb response to a wide range of recombinant AAV vectors.

The assay is based on a packaging cell line expressing a recombinant virus, containing a tag sequence within the ITRs and a serotype-specific cap gene recognized specifically by a reporter cell line stably transfected with a luciferase reporter-gene placed under the control of an AAV-responsive chimeric promoter.

10:50 LIVE PANEL DISCUSSION: Recent Advances with Novel Modalities and Managing Drug and Target Interference

Moderator: Darshana Jani, PhD, Director, Global Bioanalysis, Agenus
Panelists:
Boris Gorovits, PhD, Vice President, In Vitro Pharmacology, Biomarker Discovery and Bioanalysis, Sana Biotechnology
Kate Peng, PhD, Director/Senior Scientist, BioAnalytical Sciences, Genentech
Don Zhong, PhD, Dir Bioanalytical Sciences, Bioanalytical Sciences, Sangamo Therapeutics
John Kamerud, PhD, Director, Bioanalytical, Pfizer
Michael G. Tovey, Ph.D, Chief Scientific Advisor of Svar Life Science France, Svar Life Science

11:10 Session Break - View Our Virtual Exhibit Hall

LIVE PLENARY PANEL

11:30 Live Plenary Panel: Antibody and Vaccine Development for COVID-19




Moderator: Erica Ollmann Saphire, PhD, Professor, La Jolla Institute for Immunology

- What didn't go well during the pandemic?
- What is the future? Will there be an mRNA vaccine for influenza?
- What did we learn about our country's ability to manufacture during surge production?
- What is needed in terms of infrastructure?

Panelists:
Peter Hotez, MD, PhD, FASTMH, FAAP, Dean, National School of Tropical Medicine; Professor, Departments of Pediatrics, Molecular Virology & Microbiology; Co-Head, Section of Pediatric Tropical Medicine; Health Policy Scholar, Baylor College of Medicine
Lakshmi Krishnan, PhD, A/Vice-President, Life Sciences, National Research Council Canada, Government of Canada
Peter W. Marks, MD, PhD, Director, FDA CBER

12:15 pm Session Break - View Our Virtual Exhibit Hall

BREAKOUT DISCUSSIONS

12:30 Problem Solving Discussions

Join your colleagues and fellow delegates for a focused, informal discussion moderated by a member of our speaking faculty. A small group format allows participants to meet potential collaborators, share examples from their own work and discuss ideas with peers. See website for a full list of topics.

TABLE: Application of Immunogenicity Prediction Tools and T Cell Response

Robin E. Walsh, Consultant Toxicologist, ImmunoToxicology, Eli Lilly & Co.

- What assays are available for preclinical assessment of immunogenicity?
- What are the principles and value of each assay?
- Review the different assay formats
- How to use a weight of evidence approach to assess immunogenicity

1:10 Session Break - View Our Virtual Exhibit Hall

RISK ASSESSMENT STRATEGIES

1:20 Strategies for Immunogenicity Assessment in a Biologic Drug's Life

Linlin Luo, PhD, Director, Regulated Bioanalytical Group, Merck

The 2019 FDA guidance for immunogenicity testing emphasizes the importance of including an Integrated Summary Report of Immunogenicity in BLA submission. At Merck, we've successfully established an integrated immunogenicity strategy focusing on specific aspects at different development stages. I'll present several case studies to elaborate our risk-based immunogenicity strategy, demonstrate some challenges in ADA assay development, and exemplify how to evaluate immunogenicity data in the context of clinical relevance.

1:40 An Update on the Immunogenicity Risk-Profile for Immune Checkpoint Inhibitors in IO Trials

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

Immune Checkpoint Inhibitors (ICIs) revolutionize the cancer treatment landscape due to their impressive therapeutic results in patients with advanced malignancies. The MOA for ICIs suggested a robust ADA response. However, real clinical experience indicated that the risk of developing clinically relevant ADA response against ICIs is low and may not correlate with their MOA. This presentation will summarize the main lessons learned about the clinical relevance of ADA against ICIs.

PREDICTIVE STUDIES AND PREDICTIVE TOOLS

2:00 Predicting T Cell Immunogenicity Beyond HLA Antigen Presentation

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

Methods for prediction of HLA antigen presentation have improved substantially over the last years, and further steps for improved T cell immunogenicity prediction require consideration of T cell specificities. In my talk, I will outline recent progress in predicting T cell receptor specificities, and demonstrate how performance for prediction of protein drug T cell immunogenicity can be boosted by incorporating features of self-similarity and T cell tolerance.

2:20 A Statistical Model Using Preclinical Assay Results to Predict Anti-Drug Antibody Incidence

Richard Higgs, Senior Research Fellow, Eli Lilly & Co.

This presentation describes the construction and characterization of a statistical model to predict the incidence of anti-drug antibodies. The model was trained and evaluated using a set of over 50 clinically assessed monoclonal antibodies and integrates information from an antigen presenting cell internalization assay, an HLA-II peptide presentation assay, and a large human antibody repertoire database.

2:40 Simplify the development of single domain antibodies using the Strep-tag® platform

Dennis Karthaus, MSc, Director Protein Products & Assays, Protein Products & Assays, IBA Lifesciences

The development and screening of single domain antibodies comprises several process steps. These can be simplified by using the versatile Strep-tag® technology for the antigen production, B-cell selection, cell staining and kinetic studies. The obtained single domain antibodies will finally be used for the isolation of target cells from whole blood with IBA´s traceless affinity cell selection (TACS) technology.

3:10 LIVE PANEL DISCUSSION: Risk Assessment Strategies and Predictive Studies and Predictive Tools

Moderator: Mohamed Hassanein, PhD, Associate Director, Clinical Assay Lead (Biologics), Pfizer
Panelists:
Robin E. Walsh, Consultant Toxicologist, ImmunoToxicology, Eli Lilly & Co.
Linlin Luo, PhD, Director, Regulated Bioanalytical Group, Merck
Morten Nielsen, Professor, PhD, Department of Health Technology, Technical University of Denmark
Richard Higgs, Senior Research Fellow, Eli Lilly & Co.
Dennis Karthaus, MSc, Director Protein Products & Assays, Protein Products & Assays, IBA Lifesciences

3:30 Close of Conference

COVID INTERVENTIONS STREAM

NEW

Accelerating Coronavirus Research & Development

With confirmed COVID-19 cases worldwide surpassing 95 million and growing, scientists are working relentlessly to develop therapeutics and vaccines to slow the pandemic and halt the disease's path. The scientific community has never been more united than now, where industry, governments and NGOs are coming together to meet this unprecedented challenge. CHI's COVID Interventions Stream will bring together the stakeholders to discuss vaccine or therapeutic intervention strategies and platforms, explore partnerships for fast tracking to the clinic, scale up manufacturing and distribution.

2021 COVID INTERVENTIONS STREAM CONFERENCES

May 11-12

Therapeutic Interventions for COVID-19

AGENDA

May 12-13

Accelerating Vaccine Development for COVID-19

AGENDA

PEGSBOSTON CONFERENCE STREAMS

- ENGINEERING
- ONCOLOGY
- BISPECIFIC ANTIBODIES
- IMMUNOTHERAPY
- EXPRESSION
- ANALYTICAL
- IMMUNOGENICITY
- COVID INTERVENTIONS

MAY 11-12, 2021 | Inaugural

THERAPEUTIC INTERVENTIONS FOR COVID-19

The Race to a Cure

TUESDAY, MAY 11

NOVEL AND ALTERNATIVE APPROACHES TO DEVELOPING COVID-19 THERAPEUTICS

9:00 am Next-Generation Approaches to COVID-19 Therapeutics: Clinical Challenges and Engineering Solutions

Daniel S. Chen, MD, PhD, CMO, IGM Biosciences

As a pandemic respiratory virus, SARS-CoV-2 presents a number of challenges for emerging therapeutics. From active immune suppression, infection in different compartments and microenvironments within the host, to mutations and variants. An emerging understanding of this complex viral disease has evolved. Armed with this information, an opportunity exists to design and engineer new therapeutics that can address these findings and overcome these challenges. Examples of such approaches will be described.

9:20 Preclinical and Clinical Development of an Anti-SARS-CoV-2 Antiviral

Mark Thrun, MD, Executive Director, Global COVID-19 Team, Medical Affairs, Gilead Sciences Inc.

9:40 Preventing COVID-19 Infection Using a Safe and Approved Drug in a Long Acting Injectable Formulation

Joel Richard, PhD, Chief Development Officer, MedinCell SA

MedinCell is developing a prophylactic treatment to protect against COVID-19 infection with a long-acting injectable (LAI) formulation of Ivermectin. The objective is to achieve continuous drug dosing long periods of time. A safety clinical study is ongoing with oral Ivermectin aiming at evaluating safety and tolerability over 4 weeks in healthy volunteers. Several subcutaneous LAIs have already been shown to deliver Ivermectin over 4 weeks in animal models.

10:00 Novel Anti-SARS-CoV2 Antibody Therapy with Safety Design for Treatment of Moderate to Severe COVID-19

Thomas Schirrmann, PhD, CEO, Management & Sales & Strategy & R&D, YuMab GmbH

COR-101 is a novel SARS-CoV-2 neutralizing antibody developed by Corat Therapeutics from target to first patient in less than 10 months. COR-101 was derived from a convalescent patient and endowed with a unique safety design preventing ADE and inflammation. COR-101 shows potent virus neutralization as well as resistance to known virus mutations. COR-101 is currently investigated in a phase 1b trial of patients with moderate to severe COVID-19.

10:20 Accelerating Development of Therapeutic Interventions for COVID-19

Gaurav Agrawal, PhD, Scientific Development Manager, Eurofins DiscoverX

Millions of deaths worldwide have been attributed to COVID-19, caused by the SARS-CoV-2 virus. The high mortality rate has been associated with cytokine release syndrome, commonly referred to as cytokine storm, which is an excessive and dysregulated production of proinflammatory cytokines by patient's immune system. As a treatment strategy, a vast array of anti-inflammatory therapies are being explored and currently there are numerous clinical programs ongoing focused on developing and repurposing therapeutic drugs for treatment of COVID-19. In this talk, we highlight how our functional cell-based assays are supporting these programs, particularly in managing proinflammatory cytokines associated with high mortality rate in COVID-19 patients. We will present case studies for our target-specific, ready-to-plate qualified Bioassays, and discuss how they can accelerate drug development and QC lot release programs for biologic drugs for COVID-19.

10:50 LIVE PANEL DISCUSSION: Novel and Next-Generation Approaches to COVID-19 Therapeutics

Moderator: Daniel S. Chen, MD, PhD, CMO, IGM Biosciences
Panelists:
Joel Richard, PhD, Chief Development Officer, MedinCell SA
Thomas Schirrmann, PhD, CEO, Management & Sales & Strategy & R&D, YuMab GmbH
Mark Thrun, MD, Executive Director, Global COVID-19 Team, Medical Affairs, Gilead Sciences Inc.
Gaurav Agrawal, PhD, Scientific Development Manager, Eurofins DiscoverX

11:10 Session Break - View Our Virtual Exhibit Hall

11:10 ASK THE EXPERT with Svar Life Science

Michael G. Tovey, Ph.D, Chief Scientific Advisor of Svar Life Science France, Svar Life Science

Svar´s Expert session will focus on AAV mediated gene therapy and potential neutralizing antibody response to AAV vectors. We know the importance of precisely quantify both the neutralizing antibody response prior to treatment, and the neutralizing antibody response to the recombinant AAV vector following treatment. Talk to us about how our highly sensitive reporter-gene assays are used for the quantification of NAbs to recombinant AAV vectors with different capsid specificities.

PLENARY KEYNOTE ADDRESS

11:25 Plenary Keynote Introduction

Jennifer R. Cochran, PhD, Shriram Chair & Professor, Bioengineering & Chemical Engineering, Stanford University

11:30 KEYNOTE PRESENTATION: The Coming of Age of *de Novo* Protein Design

David A. Baker, PhD, Henrietta & Aubrey David Endowed Professor, Biochemistry, University of Washington

I will describe the *de novo* design of fluorescent proteins, membrane penetrating macrocycles, transmembrane protein channels, allosteric proteins that carry out logic operations, and self-assembling nanomaterials and polyhedra. I will also discuss the application of these methods to COVID-19 challenges.

12:00 pm Live: Q&A with Audience

Moderator: Jennifer R. Cochran, PhD, Shriram Chair & Professor, Bioengineering & Chemical Engineering, Stanford University
Panelists:
David A. Baker, PhD, Henrietta & Aubrey David Endowed Professor, Biochemistry, University of Washington

12:10 Session Break - View Our Virtual Exhibit Hall

BREAKOUT DISCUSSIONS

12:20 Problem Solving Discussions

Join your colleagues and fellow delegates for a focused, informal discussion moderated by a member of our speaking faculty. A small group format allows participants to meet potential collaborators, share examples from their own work and discuss ideas with peers. See website for a full list of topics.

TABLE: Challenges in the Development of Therapeutics & Vaccines for COVID-19

Dimiter Dimitrov, PhD, Professor and Director, Center for Antibody Therapeutics, University of Pittsburgh; Executive Vice President and CSO, Abound Bio

- How has/will this pandemic transform R&D and manufacturing of future biologics and vaccines?
- How to fight most effectively the SARS-CoV-2 mutants?
- What are the lessons learned to inform future pandemic preparedness?

1:00 Session Break - View Our Virtual Exhibit Hall

NEUTRALIZING ANTIBODIES FOR SARS-COV-2 TREATMENT

1:10 Tackling COVID-19 with Human Neutralizing Antibodies

Davide Corti, PhD, Senior Vice President, Antibody Research, Humabs BioMed, a subsidiary of Vir Biotechnology, Inc.

The development of effective countermeasures is paramount to curb the pandemic spread caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The SARS-CoV-2 spike (S) glycoprotein promotes entry into host cells and is the main target of neutralizing antibodies. In this talk Dr. Corti will present data on the key structural and functional features of multiple classes of SARS-CoV2 neutralizing antibodies isolated from COVID-19 immune donors.

1:30 Engineering Broadly Neutralizing Antibodies to Combat SARS-Like Coronaviruses

Laura M. Walker, PhD, Director, Antibody Sciences, Adimab LLC

The recurrent zoonotic spillover of coronaviruses into humans underscores the need for broadly active countermeasures. We employed a directed evolution approach to engineer SARS-CoV-2 antibodies for enhanced neutralization breadth and potency. One of the affinity matured variants neutralizes representative sarbecoviruses with remarkable potency and provides complete protection against SARS and COVID-19 disease in animal models. ADG-2 represents a promising broad-spectrum therapeutic candidate for SARS-CoV-2 and future emerging SARS-like CoVs.

1:50 Regulatory Perspectives and Learnings from the Accelerated Development of a Neutralizing Monoclonal Antibody for COVID-19

Rimple Patwardhan, PhD, Research Scientist, CMC Regulatory Affairs, Eli Lilly & Co.

The COVID-19 pandemic challenged all boundaries in scientific and regulatory communities. Every aspect was accelerated – from the clinical programs, CMC development and finally to the emergency use authorization registration process. There was great partnership between the FDA and the industry with a common goal to provide a treatment to the patients we serve. This is a opportunity to share our regulatory perspectives and learnings in an unanticipated accelerated environment.

2:10 AstraZeneca Long-Acting Antibody Combination for the Prevention and Treatment of COVID-19

Mark T. Esser, PhD, Vice President, Microbial Sciences, BioPharma R&D, AstraZeneca

This presentation will provide an overview of convalescent plasma and monoclonal antibodies currently in development for the treatment of COVID-19 with a focus on the discovery and development of AstraZeneca's long-acting antibody (LAAB) combination (AZD7442) currently being evaluated for both the prevention and treatment of COVID-19.

2:30 Fighting COVID-19 with next generation antibody discovery

Matthieu Delincé, Head of Screening, Memo Therapeutics AG

Memo Therapeutics AG has developed an advanced antibody discovery platform for the direct identification of functional antibodies from natural repertoires. The platform is used for the identification of therapeutics antibodies to treat cancer and viral infections. This presentation will introduce COVAB-36 our lead anti-SARS-CoV-2 candidate. Our antibody screening platform allowed us to identify one of the most potent SARS-CoV-2 neutralizing antibodies in just a few weeks.

2:50 Terminal Complement Inhibition Therapy for Severe COVID-19

Shamsah D. Kazani, MD, MMSc, Senior Director, Clinical Development & Translational Sciences - R&D, Alexion Pharmaceuticals, Inc.

Terminal complement amplification is a key contributor to multi-organ failure in patients with severe COVID-19. Eculizumab is a humanized monoclonal antibody that binds with high affinity to complement protein C5 and inhibits terminal complement activation. Eculizumab is being provided for patients with severe COVID-19 to requesting physicians through Experimental Emergency Treatment/Expanded Access programs. We present data demonstrating the pharmacodynamics and clinical outcomes following eculizumab therapy in patients with severe COVID-19.

3:10 Neutralizing, Protective and Convergent IgG Antibody Responses to SARS-CoV-2 in Convalescent Plasma

Gregory C. Ippolito, PhD, Research Assistant Professor, Molecular Biosciences, University of Texas at Austin

Here we present a molecular-level investigation of convalescent plasma and the constituent IgG antibodies targeting the SARS-CoV-2 Spike glycoprotein. We note that the bulk of the polyclonal plasma IgG response is directed towards non-RBD Spike epitopes. This includes NTD-directed antibodies that equal or exceed RBD-directed antibodies in abundance, potency (IC50 range 0.02–1.0 µg/mL), and protective efficacy. Our results provide a rationale for therapeutic interventions based on non-RBD Spike epitopes.

3:30 LIVE PANEL DISCUSSION: Developing Neutralizing Antibodies for SARS-Cov2 Treatment - Regulatory, Engineering and Drug Repurposing

Moderator: Gregory C. Ippolito, PhD, Research Assistant Professor, Molecular Biosciences, University of Texas at Austin

Panelists:

Davide Corti, PhD, Senior Vice President, Antibody Research, Humabs BioMed, a subsidiary of Vir Biotechnology, Inc.

Mark T. Esser, PhD, Vice President, Microbial Sciences, BioPharma R&D, AstraZeneca

Shamsah D. Kazani, MD, MMSc, Senior Director, Clinical Development & Translational Sciences - R&D, Alexion Pharmaceuticals, Inc.

Rimple Patwardhan, PhD, Research Scientist, CMC Regulatory Affairs, Eli Lilly & Co.

Laura M. Walker, PhD, Director, Antibody Sciences, Adimab LLC

Matthieu Delincé, Head of Screening, Memo Therapeutics AG

4:20 Close of Day One

3:30 SC1: CAR T Cell Therapy from A-Z SC2: Introduction to Gene Therapy Products Manufacturing and Analytics

Separate registration required. See short course page for details.

WEDNESDAY, MAY 12

GENERATING ANTIBODIES AGAINST COVID-19 BY DIFFERENT RECOMBINANT METHODS

9:00 am The Greatest Competition in Antibody History: A Naïve Library Directly Delivering Antibodies As Potent As Immune Sources

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

The SARS-CoV-2 pandemic resulted in an extraordinary worldwide unplanned experiment, in which numerous groups generated antibodies against a single target: CoV-2 spike. The most potent were generated from convalescent patients, with naïve libraries yielding significantly worse antibodies. Here we show ultra-potent (IC50 <2ng/ml) human neutralizing antibodies can be generated directly from an innovative naïve antibody library with affinities, developability properties and neutralization activities comparable to the best from hyperimmune sources.

9:20 Human Monoclonal Antibodies for Emerging Infections

James E. Crowe Jr., MD, Ann Scott Carell Chair & Professor & Director, Vaccine Center, Vanderbilt University Medical Center

Epidemics and pandemics with RNA viruses are occurring at an accelerating pace. We have embarked on a long term project to discover best-in-class human monoclonal antibodies for the 100 most likely epidemic viruses, a project called AHEAD100.

9:40 Rapid Selection, Characterization and Clinical Development of Fully-Human Antibodies against Emerging Infectious Diseases

Christos Kyratsous, PhD, Vice President, Research, Infectious Diseases & Viral Vector Tech, Regeneron Pharmaceuticals Inc.

Antibodies have become important in treating infectious diseases. We recently developed a triple antibody cocktail against Ebola virus, the first FDA approved therapy for this indication. Now, we describe the generation and characterization of an antibody cocktail against SARS-CoV-2. Early clinical data confirmed its antiviral activity and demonstrated clinical benefit by significantly reducing medical visits of symptomatic ambulatory patients. Our cocktail received Emergency Use Authorization, while clinical testing is continuing.

10:00 Therapeutic Human Monoclonal Antibodies against SARs-CoV-2 and Related Viruses

Dimiter Dimitrov, PhD, Professor and Director, Center for Antibody Therapeutics, University of Pittsburgh; Executive Vice President and CSO, Abound Bio

We rapidly identified an IgG1 and an VH-Fc which bound with high avidity to SARS-CoV-2 S glycoprotein and mutants found in patients (Li W et al PNAS, Cell 2020). They potently and specifically neutralized SARS-CoV-2 in hACE2 expressing transgenic mice and hamsters as well as mouse ACE2 adapted SARS-CoV-2 in wild type BALB/c mice at doses as low as 2 mg/kg, and are being produced for evaluation in clinical trials.

10:20 Production and optimization of protein reagents for serological mapping of the COVID-19 pandemic

Dominic Esposito, Dr., Director, Protein Expression Laboratory, Frederick National Laboratory for Cancer Research

Serology is a powerful tool for monitoring outbreaks of pandemic diseases like COVID-19. Serology assays can identify the number of asymptomatic patients and track the progress of the pandemic and vaccination campaigns. The key to COVID-19 serology assays is high-quality protein reagents including the SARS-CoV-2 spike, RBD, and nucleocapsid. We highlight production and optimization of these critical reagents to produce higher quality antigens and more sensitive assays for detection of antibodies.

10:50 LIVE PANEL DISCUSSION: Generating Antibodies Against COVID-19 by Different Recombinant Methods

Moderator: Andrew R.M. Bradbury, PhD, CSO, Specifica, Inc.
Panelists:
James E. Crowe Jr., MD, Ann Scott Carell Chair & Professor & Director, Vaccine Center, Vanderbilt University Medical Center
Dimiter Dimitrov, PhD, Professor and Director, Center for Antibody Therapeutics, University of Pittsburgh; Executive Vice President and CSO, Abound Bio
Christos Kyratsous, PhD, Vice President, Research, Infectious Diseases & Viral Vector Tech, Regeneron Pharmaceuticals Inc.
Richard Buick, Dr, CTO, Fusion Antibodies
Dominic Esposito, Dr., Director, Protein Expression Laboratory, Frederick National Laboratory for Cancer Research

11:10 Session Break - View Our Virtual Exhibit Hall

11:10 CO-PRESENTATION: ASK THE EXPERT with SCIEX

Matt Stone, Biologics Workflow Specialist, SCIEX
Mukesh Malik, Sr. Application Scientist, SCIEX

Join SCIEX analytical technology experts Matthew Stone and Mukesh Malik during an interactive Q&A session to discuss analytical development and optimization of capillary electrophoresis and liquid chromatography-mass spectrometry based methods for protein characterization and quantification. Exciting topics covered include mAbs and mAb variants, cell and gene therapy, vaccines and more!

YOUNG SCIENTIST KEYNOTE

11:25 Young Scientist Keynote Introduction

Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute

11:30 KEYNOTE PRESENTATION: Cryo-Electron Microscopy Structures of Spike Glycoproteins Suggest Pan-Coronavirus Antiviral Strategy

Christine Toelzer, Research Associate, University of Bristol, United Kingdom

We research antivirals to combat present and future coronavirus pandemics. We discovered linoleic acid bound to a hydrophobic pocket in the Cryo-EM structure of the SARS-CoV-2 Spike glycoprotein. Ligand binding locked the protein in a compact closed conformation. Conservation of key AA residues suggested a similar pocket exists in other pathogenic coronaviruses.

12:00 pm Live: Q&A with Young Scientist Keynote

Moderator: Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute
Panelists:
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

1:00 Close of Therapeutic Interventions for COVID-19 Conference

12:10 Session Break - View Our Virtual Exhibit Hall

ACCELERATING VACCINE DEVELOPMENT FOR COVID-19

Partnerships for R&D to Clinic and Beyond

WEDNESDAY, MAY 12

YOUNG SCIENTIST KEYNOTE

11:25 am Young Scientist Keynote Introduction
Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute

11:30 KEYNOTE PRESENTATION: Cryo-Electron Microscopy Structures of Spike Glycoproteins Suggest Pan-Coronavirus Antiviral Strategy
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

We research antivirals to combat present and future coronavirus pandemics. We discovered linoleic acid bound to a hydrophobic pocket in the Cryo-EM structure of the SARS-CoV-2 Spike glycoprotein. Ligand binding locked the protein in a compact closed conformation. Conservation of key AA residues suggested a similar pocket exists in other pathogenic coronaviruses.

12:00 pm Live: Q&A with Young Scientist Keynote
Moderator: Kent Simmons, Senior Conference Producer, Cambridge Healthtech Institute
Panelists:
Christine Toelzer, Research Associate, University of Bristol, United Kingdom

12:10 Session Break - View Our Virtual Exhibit Hall

PARTNERSHIPS TO ACCELERATE COVID-19 VACCINE DEVELOPMENT

1:10 KEYNOTE PRESENTATION: Development and Manufacturing of COVID-19 Vaccines in a Pandemic Situation
Anna Särnefält, Lead, Chemistry & Mfg & Controls, CEPI

Since January 2020 vaccine developers around the world have undertaken measures to deliver safe and efficient vaccines to combat the pandemic. We have seen unprecedented efforts to make vaccines available at shortest possible time, accelerating timelines and taking multiple actions at risk. Through COVAX, CEPI is committed to deliver 2 billion doses by the end of 2021 and this presentation will address work supporting the COVAX motto: Speed, Scale, Access.

1:30 An Innovative Partnership Model to Accelerate Development of V590 – A Recombinant VSV SARS-CoV-2 Vaccine Candidate
Swati Gupta, DrPH, MPH, Vice President & Head, Emerging Infectious Diseases & Scientific Strategy, IAVI

Merck and IAVI are collaborating to develop an investigational vaccine against SARS-CoV-2 which combines the vaccine R&D capabilities of both organizations and uses the same rVSV platform as Ervebo, the first rVSV-based licensed vaccine for prevention of Ebola Zaire. V590 has generated strong preclinical data and clinical studies are ongoing. The organizations are working in an innovative partnership to accelerate the vaccine's development and make it accessible globally, if approved.

NOVEL VACCINE TECHNOLOGIES AND APPROACHES

1:50 INO-4800 – A DNA-Based Vaccine Against COVID-19
Kate E. Broderick, PhD, Senior Vice President, R&D, Inovio Pharmaceuticals, Inc.

The synthetic DNA vaccine INO-4800 is being developed as a medical countermeasure to prevent COVID-19. Clinical studies are currently ongoing and have revealed the INO-4800 induces broad immune responses which neutralize the virus. Importantly, vaccination with INO-4800 has a very favorable safety profile, and the thermostability of the synthetic DNA allows for simplified global distribution and storage.

2:10 A Novel COVID-19 mRNA Vaccine from RNAimmune
Dong Shen, MD, PhD, President & CEO, RNAImmune, Inc.

Two mRNA vaccines from Pfizer and Moderna are authorized for emergency use and both work by rewiring a genetic trigger. SARS-CoV-2, the virus that causes COVID-19 (coronavirus), has a unique physical structure that can be used to prime immune response. An mRNA vaccine has never been approved before, but other mRNA drugs exist. RNAimmune has developed a third generation mRNA vaccine which targets most known mutations.

2:30 Contrasting total IgG binding assays with a high-throughput neutralizing antibody test in a COVID post-vaccination era
Sean Taylor, Dr., Manager, Field Application Scientist, Catalog Products, GenScript

A new, SARS-CoV-2, high-throughput, ELISA-based neutralizing antibody test will be described. The comparative accuracy of pre-existing EUA authorized SARS-CoV-2 IgG binding and functional neutralizing antibody serology tests in detecting natural infection/recovered individuals is contrasted. SARS-CoV-2 vaccine efficacy and evidence correlating neutralizing antibodies with potential protection will be reviewed. Finally, some new data comparing functional neutralizing versus total IgG binding antibody responses to vaccination will be presented.

3:00 LIVE PANEL DISCUSSION: Leveraging Industry, Academia & Government Partnerships to Accelerate COVID-19 Vaccine Development
Moderator: Anna Särnefält, Lead, Chemistry & Mfg & Controls, CEPI
Panelists:
Kate E. Broderick, PhD, Senior Vice President, R&D, Inovio Pharmaceuticals, Inc.
Swati Gupta, DrPH, MPH, Vice President & Head, Emerging Infectious Diseases & Scientific Strategy, IAVI
Dong Shen, MD, PhD, President & CEO, RNAImmune, Inc.
Sean Taylor, Dr., Manager, Field Application Scientist, Catalog Products, GenScript

3:20 PEGS Connects - View Our Virtual Exhibit Hall

3:30 SC3: Developability of Bispecific Antibodies: Formats and Applications
Separate registration required. See short course page for details.

4:00 Close of Day

THURSDAY, MAY 13

NOVEL VACCINE TECHNOLOGIES AND APPROACHES

9:00 am UB-612, a Novel Multitope Protein/Peptide-Based Vaccine against SARS-CoV-2
Farshad Guirakhoo, PhD, CSO, Covaxx and Vaxxinity

UB-612 is the first multitope protein-peptide vaccine against SARS-CoV-2, the pathogen. UB-612 consists of eight components rationally designed for induction of high neutralizing antibodies and broad T cell responses against SARS-CoV-2: In preclinical models the vaccine induced high titers of neutralizing and a Th1-oriented T cell response and was protective in challenge studies. Phase 1 trial is being completed and phase 2/3 global efficacy trials will start in Q1 2021.

9:20 CoVepiT, a Second-Generation COVID-19 Vaccine with a Multi-Target Approach Focused on CD8 T-Cell Epitopes
Nicolas Poirier, PhD, CSO, OSE Immunotherapeutics

CoVepiT is a multi-target CD8 T cell epitopes SARS-CoV-2 vaccine which demonstrates induction of tissue-resident memory T cells in the lung and airways tissues after subcutaneous injection. CoVepiT has potential for an universal vaccine against coronaviruses (including all previous, currently circulating and future mutated SARS-CoV-2 variants).

9:40 Use of the BCG Vaccine as a Platform to Protect from Diverse Infectious Disease: The Data for COVID-19 Infections

Denise L. Faustman, MD, PhD, Associate Professor & Director, Immunobiology Labs, Massachusetts General Hospital

There is an emphasis on pathogen directed vaccines. An alternative approach is a vaccine that overall boost the immune system such as the BCG vaccine. There are 22 clinical trials using the BCG vaccine to induce immunity to COVID. The advantages of the BCG vaccine are multiple. The BCG vaccine is cost-effective approach, may last decades and protects from all mutant versions of the virus.

10:00 Use of Platform Technologies for the Development of COVID-19 Vaccines

Dinja Oosterhoff, PhD, Program Director, Intravacc

Intravacc develops several COVID-19 vaccines based on its platform technologies, like outer membrane vesicle (OMV) technology and Vero Cell technology. For the OMV-based vaccines, either T cell epitopes of SARS-CoV-2 or modified spike protein are coupled to the OMVs, whereas a Newcastle disease viral vector vaccine is developed on the Vero cell platform. In this presentation, Dinja will introduce and present the status of the different SARS-CoV-2 vaccine concepts.

10:20 Analytical tools for the accelerated study and fight against COVID-19

bio-techne

Chris Heger, Ph.D., Director Applications Science, Applications Science, ProteinSimple, a Bio-Techne brand

Bio-Techne has worked tirelessly for the past year to enable our customers to research, characterize, and develop therapies against the novel SARS-CoV-2 virus. Efforts have produced a wide portfolio of important reagents and analytical tools. I will discuss how we leveraged our own SARS-CoV-2 recombinant proteins and antibodies to rapidly generate fast, reproducible, and sensitive assays on our Simple Western and Simple Plex platforms to characterize the immune response in COVID-19.

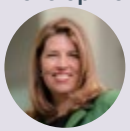
10:50 LIVE PANEL DISCUSSION: Novel & Alternative Approaches to Developing COVID-19 Vaccines

Moderator: Denise L. Faustman, MD, PhD, Associate Professor & Director, Immunobiology Labs, Massachusetts General Hospital
Panelists:
Farshad Guirakhoo, PhD, CSO, Covaxx and Vaxxinity
Chris Heger, Ph.D., Director Applications Science, Applications Science, ProteinSimple, a Bio-Techne brand
Dinja Oosterhoff, PhD, Program Director, Intravacc
Nicolas Poirier, PhD, CSO, OSE Immunotherapeutics

11:10 Session Break - View Our Virtual Exhibit Hall

LIVE PLENARY PANEL

11:30 Live Plenary Panel: Antibody and Vaccine Development for COVID-19




Moderator: Erica Ollmann Saphire, PhD, Professor, La Jolla Institute for Immunology

- What didn't go well during the pandemic?
- What is the future? Will there be an mRNA vaccine for influenza?
- What did we learn about our country's ability to manufacture during surge production?
- What is needed in terms of infrastructure?

Panelists:
Peter Hotez, MD, PhD, FASTMH, FAAP, Dean, National School of Tropical Medicine; Professor, Departments of Pediatrics, Molecular Virology & Microbiology; Co-Head, Section of Pediatric Tropical Medicine; Health Policy Scholar, Baylor College of Medicine
Lakshmi Krishnan, PhD, A/Vice-President, Life Sciences, National Research Council Canada, Government of Canada
Peter W. Marks, MD, PhD, Director, FDA CBER

12:15 pm Session Break - View Our Virtual Exhibit Hall

BREAKOUT DISCUSSIONS

12:30 Problem Solving Discussions

Join your colleagues and fellow delegates for a focused, informal discussion moderated by a member of our speaking faculty. A small group format allows participants to meet potential collaborators, share examples from their own work and discuss ideas with peers. See website for a full list of topics.

1:10 Session Break - View Our Virtual Exhibit Hall

COMPUTATIONAL DESIGN, RISK AND BIOMARKER ASSESSMENT

1:20 Combined Forces, Targeting the Spike with Computational Design and High-Throughput Experimental Screening

Eva-Maria Strauch, PhD, Assistant Professor, Pharmaceutical & Biomedical Sciences, University of Georgia

Our lab is working on establishing a novel platform for the generation of antivirals and vaccine candidates using both computational structural design and high-throughput experimental screening using surface display methods to address emerging infectious disease. We are employing deep mutational scanning to explore fitness landscapes of the Spike protein. We are using computational structural design methods we developed to stabilize specifically the pre-fusion conformation of viruses.

1:40 Assessment of Individual- and Community-Level Risks for COVID-19 Mortality in the US and Implications for Vaccine Distribution

Nilanjan Chatterjee, PhD, Bloomberg Distinguished Professor, Biostatistics, Johns Hopkins University

2:00 The Frequency of SARS-CoV-2 Specific Memory B Cells in COVID-19 Recovered Patients Remain Stable while Antibodies Decay over Time

Yariv Wine, PhD, Assistant Professor, The Shmunis School of Biomedicine and Cancer Research, Tel Aviv University, Israel

- Antibody levels in COVID-19 recovered patients decay over a period of six months.
- RBD^+ IgG levels can be used as a proxy to evaluate neutralizing IgG.
- Following recovery, RBD^+ mBC frequency remains stable over a period of six months.
- Next-generation sequencing of RBD^+ B cell receptors showed an unregular high frequency of the IgG4 isotype which is known to contribute to the manifestation of IgG4-related disease.

2:20 Markers of Polyfunctional SARS-CoV-2 Antibodies in Convalescent Plasma and Mucosa

Harini Natarajan, PhD Student, Microbiology & Immunology, Dartmouth College

There is an immediate need to understand the mechanisms of protection against SARS-CoV-2 infection. In this work, we have profiled serum, plasma, and mucosal antibody responses to SARS-CoV-2. Further, we examined the role of cross-reactive immunity in SARS-CoV-2 infection and how exposure to endemic coronaviruses could impact responses to SARS-CoV-2. Collectively, these results may contribute to the development of novel vaccines or therapeutics for COVID-19.

2:40 Making Vaccines in Large Quantities, Flexible Commercial Scales more Affordable-C1 Cells

DYADIC

Mark Emalfarb, Chief Executive Officer, Dyadic International, Inc.

3:10 LIVE PANEL DISCUSSION: Combining NGS, Modeling and Computational Design to Better Understand SARS-CoV-2 Mechanisms and Risks

Moderator: Yariv Wine, PhD, Assistant Professor, The Shmunis School of Biomedicine and Cancer Research, Tel Aviv University, Israel
Panelists:
Nilanjan Chatterjee, PhD, Bloomberg Distinguished Professor, Biostatistics, Johns Hopkins University
Mark Emalfarb, Chief Executive Officer, Dyadic International, Inc.
Harini Natarajan, PhD Student, Microbiology & Immunology, Dartmouth College
Eva-Maria Strauch, PhD, Assistant Professor, Pharmaceutical & Biomedical Sciences, University of Georgia

3:30 Close of Conference

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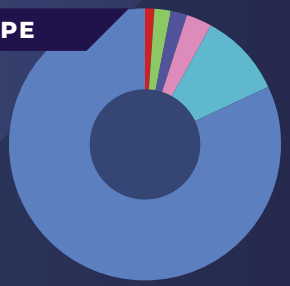
Other	1%



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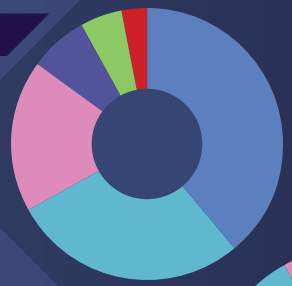

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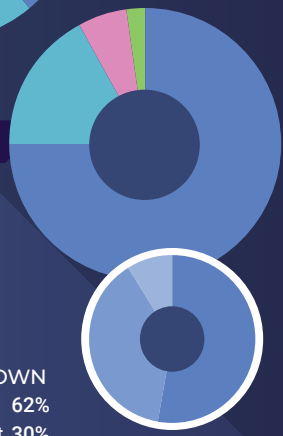

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