

FESTIVAL OF BIOLOGICS USA



San Diego Convention Center, April 23-24 2025

Festival of Biologics Advisory Board:

Alain Beck, Senior Director, Biologics CMC and Developability, **Pierre Fabre**, Associate Editor, *mAbs*

Alexander Eggermont, Chief Scientific Officer, **Princess Máxima Center for Pediatric Oncology**

Kamal Puri, Chief Scientific Officer, **OncoResponse**

Krishna Allamneni, Chief Development Officer, **Concarlo Therapeutics**

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Stefan Zielonka, Director, Protein Engineering and Antibody Technologies, Discovery Technologies | Global Research and Development, **Merck**

Bhargava Nemmaru, Senior Scientist, Drug Substance Process Development, **Amgen Inc.**

Parastoo Azadi, Technical Director of Analytical Service and Training, **Complex Carbohydrate Research Center/University of Georgia**

Julio Baez, Industrial Advisor and Consultant Bioprocessing, University of California, **San Diego**

Stanton Mehr, Principal, **Biosimilars Review and Report**

Sophia Humphreys, Executive Director, System Pharmacy, **Providence Health**

Confirmed & Reserved Speakers:

Aiying Yu, Senior Scientist, **Genentech**
Abhinav Gupta, Senior Machine Learning Scientist, **Sanofi**
Adeleh Taghi Khani, Senior Scientist II, **Quest Diagnostics**
Adrian Guzman, co-founder and CTO, **HelioWave Technologies Inc.**
Ahmed Hamdy, CEO/Founder, **Vincerx Pharma**
Alessandro Sette, Center Head, Division Head, And Professor, **La Jolla Institute**
Aline de Almeida Oliveira, Scientist and Analyst, Competitive Intelligence Office, **BIO-MANGUINHOS**
Allison Ramiller, Product Manager, Prize Design, **XPRIZE**
Alona Kiricenکو, Molecular Biology Scientist/Study Director, **SGS**
Amber Freed, CEO and Founder, **SLC6A1**
Angela Specht, Global Head, BARDA Alliance, **Johnson & Johnson Innovation**
Anupurna Kaul, Senior Scientist, **Amgen**
Andrew DiChiara, Senior Scientist II, **Abbvie**
Andrew Tsourkas, Co-Director, Center for Targeted Therapeutics and Translational Nanomedicine; Professor, Bioengineering, **University of Pennsylvania**
Aniket Badkar, Director, Formulation and Drug Product Development, **Vir Biotechnology**
Ankit Mahendra, Senior Principal Scientist, Lab Head, Antibody Platform, **Sanofi**
Armine Galstyan, Head of North American Operations, **Smart Gate VC**
Barry Chester, Global Commercial Lead – Supportive Care Oncology, **Pfizer**
Brandon DeKosky, Associate Professor, **Massachusetts Institute of Technology/The Ragon Institute**
Brandon Ruotolo, Professor, Chemistry, **University of Michigan**
Brenda Baker, Executive Director, **Ionis Pharmaceuticals**
Bruce Keyt, CSO, **Multivalent Biosciences**
Bruce Riser, CEO/CSO, **BLR Bio**
Caroline Barelle, CEO & Co-Founder, **Elasmogen**
Chad Pettit, Executive Director Global Government Affairs, **Amgen**
Chris Mason, Professor, Cell and Gene Therapy, **UCL**
Changyun (Eric) Hu, CSO & Co-Founder, **Adept Therapeutics**
Chayne Piscitelli, Principal Scientist & Group Lead, **Zymeworks**
Christian Rohlf, CEO, **Oxford BioTherapeutics**
Craig Burton, Senior Vice President of Policy, **Association of Accessible Medicines**

David Grandy, Senior Scientist, **Merck**
David Wood, Professor, Chemical and Biomolecular Engineering, **Ohio State University**
David Younger, Co-Founder and CEO, **A-Alpha Bio**
Derrick Katayama, Lead Scientist, Formulation, **Samsung Biologics**
Diane Simeone, Director, **Moore's Cancer Center**
Dikran Khachadourian, Field Application Scientist, **Halo Labs**
Dracey Poore, MSN, Director of Biosimilars **Cardinal Health**
Eeshit Dhaval Vaishnav, Founder & CEO, **Sequome**
Emily Botto, Research Analyst, **Tufts University School of Medicine**
Emilee Knowlton, Senior Immunology Sales Specialist, **ProlImmune**
Esohe Idusogie, Head, Process Quality & CMC Analytical, **ADC Therapeutics**
Farah Sheikh, Professor of Medicine, **University of California San Diego**
Felix Kuhne, Process Development Scientist, **Roche**
Fouad Atouf, Senior Vice President, **United States Pharmacopeia**
Gang Liu, Associate Director, **Biointron Biological**
Gordon Freeman, Professor of Medicine, Harvard Medical School, **Dana-Farber Cancer Institute**
Hana Do, Research Analyst, **Tufts University**
Hans van der Vliet, CSO, **Lava Therapeutics**
Henry Nguyen, Senior Scientist I, Protein Engineering, **Asher Biotherapeutics**
Hetal Patel, Senior Director, Medical Science Liaison, **Celltrion Healthcare**
Huub Gelderblom, Director of Strategic Partnerships, **Fred Hutchinson Cancer Center**
Ildiko Csiki, Chief Medical Officer, **Geneos**
Isabelle Lehoux, Director, Protein Biochemistry, **Gilead**
Jake Chen, Professor, **University of Alabama at Birmingham**
Jakub Tomala, Research Assistant Professor, **John Hopkins University**
Jan Schnitzer, President & CEO, **Proteogenomics Research Institute for Systems Medicine (PRISM)**
Jae Sly, Chief Business Development Officer, **Obatala Sciences**
Javier Chaparro-Riggers, Executive Director, **Pfizer**
Jay Mandrekar, Professor of Biostatistics and Neurology, **Mayo Clinic**
Jeff Rapp, Director, **University of Georgia**
Jennifer Johnston, CEO, **NYSNObio**
Jenny Wei, Head of R&D Informatics and Technology, **Kite Pharma**
Jeroen Hofenk, Co-Founder and CSO, **SwiftPharma**

Jingjing Jiang, Senior Director, Development Sciences, **Bambusa Therapeutics**
John Lippincott, Senior Vice President of Therapeutic Discovery Strategies, **Alloy Therapeutics**
John Lesnick, Senior Field Application Scientist, **Sphere Bio**
John Mattison, Operating Partner, Chief Medical Information Officer, **Arsenal Capital**
Joseph Fuhr, Professor Emeritus of Economics, **Widener University**
Joshua Justice, Proteomics Scientist, **Johnson & Johnson**
Judy Chou, President and CEO, **Altru**
Julio Baez, Industrial Advisor and Consultant Bioprocessing, **University of California, San Diego**
June Guo, Director of Data Engineering and Machine Learning, **Athos Therapeutics**
Jyothsna Visweswaraiyah, Director, Biotherapeutics, Drug Creation, **Seismic Therapeutic**
Kamal Puri, Chief Scientific Officer, **Oncoresponse**
Keiichiro "Kei" Kushiro, Director of Research, **Mucommune**
Kathleen Lin, Site Head, **Eli Lilly Gateway Labs**
Kevin Knopf, Chairman Hematology and Oncology, **Highland Hospital**
Kevin Zen, Senior Director, **IGM Biosciences**
Kim Walker, Faculty Director, **San Diego State University**
Koen Dierckx, Co-founder and CEO, **Simabs**
Krishna Allamneni, Chief Development Officer, **Concarlo Therapeutics**
Kyle Hoffman, Applications Manager, **Bioinformatics Solutions**
Dr Lei Shi, SVP, **Biointron Biological**
Lauri Peil, Key Account Manager and Technology Officer, **Icosagen**
Leah Villegas, Venture Partner, **Aquillius Ventures**
Leon Pybus, Associate Director, **FUJIFILM Diosynth Biotechnologies**
Linlin Guo, Assistant Professor, **Indiana University**
Liviu Movileanu, Professor, Department of Physics, **Syracuse University**
Madison Ford, Research Analyst, **Tufts University**
Mary Banach, Chair, **DIA CDM Community**, Project Manager CTSpedia Safety Graphics **VUMC**
Mary Dwyer, Director, **KACTUS**
Maryam Raeeszadeh-Sarmazdeh, Assistant Professor, **University of Nevada**
Marvin Gee, VP Target Discovery, **3T Biosciences**
Matt Bailey, Senior Scientist, **Aptevo Therapeutics**
Matthew Bernett, Executive Director, Protein Engineering, **Xencor**
Matteo Levisetti, Chief Medical Officer, **Cue Bio**

Matthew Metzger, Program, Alliance and Business Manager, **Oxford BioTherapeutics**
Melody Chang, Vice President of Pharmacy Operations, **American Oncology Network**
Michael Brehm, Associate Professor of Molecular Medicine, **University of Massachusetts**
Michael Sarshad, Managing Director, **Syneos Health Consulting; Biosimilar Consortium Commercial Lead**
Michael Sumner, Chief Medical Officer, **Inovio Pharmaceuticals**
Net Haskins, Scientist II, Protein Engineering, **Amgen**
Nicholas Marshall, Head of Protein Sciences, **Invenra**
Omer Butt, VP, Regulatory Affairs, **CytoImmune Therapeutics**
Oscar Segurado, Chief Medical Officer, **ASC Therapeutics**
Pascal Krotee, Principal, **Rivervest Venture Partners**
Patrizia Porazzi, Senior Research Investigator, Haematology and Oncology, **University of Pennsylvania**
Philip Arlen, President And Chief Executive Officer, **Precision Biologics**
Phong Tran, President and CEO, **SirnaMed Therapeutics Inc**
Prasad Adusumilli, Deputy Chief, Thoracic Surgery, Vice Chair, Department of Surgery, **MSKCC**
Prasun Chakraborty, Founder and CEO, **Genevation**
Qiang (Shawn) Chen, Professor, **Arizona State University**
Rachael Kim, CEO, **My Comma**
Rajarsi Gupta, Assistant Professor, **Stony Brook Medicine**
Robert Dillman, Chief Medical Officer, **AIVITA Biomedical**
Roelof Rongen, Co-Founder & Board Member, **Stealth**, CEO, **Adolore BioTherapeutics**
Sabrina Leslie, Associate Professor, Physics and Astronomy Department, **University of British Columbia**
Salome Philip, CMC Project Manager, **Attralus**
Sam Lai, Professor, Division of Pharmacoengineering and Molecular Pharmaceutics, **UNC Chapel Hill**
Samina Qureshi, International Medical Officer, **MedDRA MSSO**
Samuel Zhang, Chief Business Officer, **Innovent Biologics**
Sandy Yan, Head of US Regulatory Affairs, **Shanghai Henlius**
Savita Nair, Associate Director, CMC Bioassay Analytical Development, **Sangamo Therapeutics**
Scott Grealich, Senior Research Scientist, **Immunis Inc**
Scott Mack, Principal Scientist, **SCIEX**
Sean McGowan, Vice President, Biosimilars, **Amneal Pharmaceuticals Senior Representative, Abzena**

Senior Representative, Genovac
Senior Representative, Icosagen
Senior Representative, Sandoz
Senior Representative, SGS
Shamekka Marty, Patient and Advocate
Shanelle Gabriel, Patient and Advocate
Shawn Levy, SVP of Scientific Affairs, **Cellanome**
Sheng Zhong, Professor, **UCSD**
Shwetha Iyer, Biotherapeutics Formulation Lab Head, **Novartis**
Sophia Humphreys, Executive Director, System Pharmacy, **Providence Health**
Spencer Marsh, Chief Scientific Officer, **The Tiny Cargo Company**
Srikanth Kotapati, Associate Director, **Neurocrine**
Stan Mehr, Principal, **Biosimilars Review & Report**
Steve O'Malley, President, **Petauri Advisors**
Steven Lehrer, Managing Director, **SB Lehrer LLC**
Steven Quayle, Vice President & Head of Research Biology and Translational Medicine, **Cue Bio**
Sudhakar Voruganti, Director, Business Development, **Pfansthiel Inc**

Tero-Pekka ALastalo, CEO, **Avenue Biosciences**
Tzvika Hartman, SVP Computation, **BioLojic Design**
Vibha Jawa, Executive Director, **BMS**
Volker Schellenberger, SVP Research Oncology, **Vir Biotechnology**
Wenshe Liu, Professor in Chemistry, **Texas A&M University**
Xiaocheng Chen, Vice President, Antibody Therapeutics, **Virtuoso Therapeutics**
Yemi Onakunle, Founder and CEO, **Mab Switch Inc**
Yang Shen, Executive Director, Antibody Engineering & Bispecifics, **Regeneron**
Yi-Hsiang Hsu, Director and associate Professor, **Broad Institute of MIT and Harvard**
Yinyin Li, Principal Scientist, **Genentech**
Yu Zhou, Manager, Analytical Development, **Millipore Sigma**
Yuanhui Ma, Senior Research Scientist I, **Gilead**
Yue Zhao, Principal Scientist, **Genentech**
Zachary Bornholdt, CEO, **Eitr Biologics**
Zoran Kronic, Senior Manager Data Science, R&D, **Amgen**

DAY 1							
8:00am	Registration opens						
	Opening Plenary KEYNOTE THEATER						
9:00am	Welcome from Terrapinn						
9:05am	Chairs opening remarks: Chris Mason, Professor, Cell and Gene Therapy, UCL						
9:10am	CAR T Cell Therapy: New Developments and Clinical Trials Results Prasad Adusumilli, Deputy Chief, Thoracic Surgery, Vice Chair, Department of Surgery, MSKCC						
9:35am	Discovery and Development of Monoclonal Antibodies Targeting Tumor Specific Neo-epitopes Philip Arlen, President and Chief Executive Officer, Precision Biologics						
10:00am	Advances in antibody-based approaches to checkpoint inhibition Gordon Freeman, Professor of Medicine, Harvard Medical School, Dana-Farber Cancer Institute (CONFIRMED)						
10:35am	Networking Break						
	Antibody Keynotes KEYNOTE THEATER	Immunotherapy Keynotes THEATER 9	Bioprocessing: Upstream & Process Development – Downstream Processing SHOWCASE THEATER	WORKSHOP THEATER 1	Biosimilars Roundtables	Manufacturing Roundtables	Clinical Trials Roundtables
	Chair: Brandon DeKosky, Associate Professor, Massachusetts Institute of Technology/The Ragon Institute	Chair: Pamela Contag, CEO, Bioeclipse Therapeutics	Chair: Achinta Bordoloi, Research Scientist, OU Bioprocessing Institute, University of Oklahoma	10:40am-12:40pm	Roundtable session runs from 11:30-12:35		
11:30am	How delivery barriers passively limit and actively boost solid tissue targeting and therapeutic index of small to large biologics Jan Schnitzer, Director, Proteogenomics Research Institute for Systems Medicine (PRISM); UCSD (CONFIRMED)	Antigen-Specific T cell Engagement in Oncology Matteo Levisetti, Chief Medical Officer, Cue Bio	11:30-11:50 Commercial Biomanufacturing: Evolution, Adaptation, and the Survival of the Fittest Marco Mirata, Director, Head of Microbial Manufacturing Science and Technology (MSAT), Lonza	2025 Doubling Down on Women and Health <ul style="list-style-type: none"> Krishna Allamneni, Chief Development Officer, Concarlo Therapeutics Allison Ramiller, Product Manager, Prize Design, XPRIZE Rachael Kim, CEO, My Comma Armine Galstyan, Head of North American Operations, Smart Gate VC Leah Villegas, Venture Partner, Aquillius Ventures Mo Kagalwala, Venture Partner, Aquillius Ventures Anne Lynch, Research Associate, Hologic 	TABLE 1 Challenges in the development and manufacturing of Biosimilars Julio Baez, Industrial Advisor and Consultant Bioprocessing, University of California, San Diego (Confirmed)	TABLE 5 Sustainability of the US Biosimilar Market Sophia Humphreys, Executive Director, System Pharmacy, Providence Health	TABLE 9 Working with Patient Organizations for Clinical Trial Design Amber Freed, CEO and Founder, SLC6A1
11:55am	TRAILBody: A New Class of Antibody Drugs To Treat Cancer and Beyond Shiva Bhowmik, Founder and CSO, Trio Pharmaceuticals	Genetic Therapies for Inherited Retinal Diseases Daniel Chung, Chief Medical Officer, Sparing Vision	11:50-12:10 From Innovation to Evolution: Advancing Samsung Biologics' Development Platforms Derrick Katayama, Lead Scientist, Formulation, Samsung Biologics		TABLE 2 Insights into Biosimilar Policy Bret Jackson, President, Economic Alliance for Michigan (Confirmed)	TABLE 6 Formulation strategies Shwetha Iyer, Biotherapeutics Formulation Lab Head, Novartis (CONFIRMED)	TABLE 10 Quality and Trial Readiness Cheryl Marcotte, Senior Director, TA Quality Team Lead, GSK
12:20pm	Keynote panel discussion: Antibodies in Review: Lessons from 2024 and Industry Trends in 2025 <ul style="list-style-type: none"> Exploring the current state of antibody modalities and emerging therapeutics Challenges in the industry The potential of AI across the value chain Moderator: Jonathan Davis, Founder and Principal Consultant, Creative Antibodies <ul style="list-style-type: none"> Bruce Keyt, CSO, Multivalent Biosciences 	Keynote panel discussion: Cutting-edge Innovations in Immunotherapies <ul style="list-style-type: none"> Innovations in bi-specific antibodies, cellular therapies & checkpoint inhibitors <ul style="list-style-type: none"> Robert Dillman, Chief Medical Officer, AIVITA Biomedical Roelof Rongen, Co-Founder & Board Member, Stealth Philip Arlen, President and Chief Executive Officer, Precision Biologics 	12:10-12:30 Building a robust compliance infrastructure to meet pre-use post sterilization filter integrity testing (PUPSIT) requirements in a revised Annex 1 world Ross Turmell, Principal Scientist, Cytiva MSAT		TABLE 3 Global Regulatory Harmonization Hillel Cohen, Scientific Advisor, The Biosimilars Forum (confirmed)	TABLE 7 Process development for antibody manufacturing	TABLE 11 Risk Based Quality Management Sathya Ramnath, Senior manager for Risk Based Quality Management, Gilead
			12:30-12:50 Industrial Manufacturing of cGMP-grade Milk Extracellular Vesicles Spencer Marsh, CSO, The Tiny Cargo Company		TABLE 4 Barriers to Entry for Uptake Joseph Fuhr, Professor Emeritus of	TABLE 8 Drug substance development in biologics	

	<ul style="list-style-type: none"> • Volker Schellenberger, SVP Research Oncology, Vir Biotechnology • Vibha Jawa, Executive Director, BMS • Judy Chou, President and CEO, AltruBio Inc. 	Moderator: Prasad Adusumilli , Deputy Chief, Thoracic Surgery, Vice Chair, Department of Surgery, MSKCC						Economics, Widener University (Confirmed)			
	<i>Presentations continue in the Antibody and Immunotherapy Keynotes</i>										
1:00pm	Networking Break & Showcase Presentations										
	SHOWCASE PRESENTATIONS SHOWCASE THEATER 1:00pm – Path to IND for biologics: From DNA to clinical trials in just 9-months Elena Gontarz , Head of Scientific and Technical Affairs, Thermo Fisher 1:20pm – The Playbook for First-in-Human: No Shortcuts. Just Smart Scaling Alejandro Preciado , Sr. Director, Business Development, KBI Biopharma 1:40pm – Next-Generation Magnetic Separation – Streamlining Process automation Steve Glavas , Business Development Manager, MAGic Bioprocessing 2:00pm – The roadmap towards continuous manufacturing and realtime release of biologics Koen Dierckx , Co-founder and CEO, Simabs										
	Protein Engineering THEATER 8	Armed Antibodies THEATER 7	Bispecifics & Multispecifics THEATER 6	CMC & Developability THEATER 5	Antibodies for Immunotherapy <i>Combined Antibody-Immunotherapy session</i> KEYNOTE THEATER	AI and Machine Learning for Discovery <i>Combined Antibody-Immunotherapy session</i> THEATER 4	Cell Therapy THEATER 9	Therapeutic Vaccine Development & mRNA THEATER 2	Biosimilar Market Sustainability THEATER 1	Biosimilars in Healthcare Systems THEATER 3	Formulation SHOWCASE THEATER
	Chair: Nicholas Marshall , Head of Protein Sciences, Invenra	Chair: Audrey Arjomandi , Senior Principal Scientist, Genentech	Chair: Yang Shen , Executive Director, Antibody Engineering & Bispecifics, Regeneron	Chair: Ravish Patel , General Manager-Technical Operation, Kodo Lifescience	Chair: Oliver Hill , Senior Director Protein Engineering, Yumab (CONFIRMED)	Chair: Anupam Aich , Product Definition Lead, Roche	Chair: Mark Mamula , Professor of Medicine, Yale	Chair: Prasun Chakraborty , Founder and CEO, Genevation	Chair: Ivo Abraham , Professor of Pharmacy, Medicine and Clinical translational sciences, University of Arizona	Chair: Hetal Patel , Vice President, Medical Affairs, Celltrion Healthcare	Chair: Sabrina Leslie , Associate Professor, Physics and Astronomy Department, University of British Columbia
2:20pm	Personalized T cell recruiting bispecific antibodies for treating cancer Andrew Tsourkas , Co-Director, Center for Targeted Therapeutics and Translational Nanomedicine; Professor, Bioengineering, University of Pennsylvania (CONFIRMED)	Development of Next Generation of ADCs Using Novel Expression Platform and Precise Conjugation Miao Wen , Director of Protein Sciences, Sutro Biopharma (CONFIRMED)	Developing Bispecific T cell engagers against novel pHLA Targets Marvin Gee , VP Target Discovery, 3T Biosciences (CONFIRMED)	Advancing Genomic Medicine: Navigating Challenges in CMC Potency Assay development throughout the product life-cycle Savita Nair , Associate Director, CMC Bioassay Analytical Development, Sangamo Therapeutics (CONFIRMED)	Multivalent and Multispecific IgMs present unique opportunity and challenge as a therapeutic modality Bruce Keyt , CSO, Multivalent Biosciences (CONFIRMED)	AI/ML Augmented CAR Discovery Jenny Wei , Head of R&D Informatics and Technology, Kite Pharma (CONFIRMED)	A personal cancer immunotherapy platform for therapeutic vaccines targeting tumor-initiating cells Robert Dillman , Chief Medical Officer, Aivita Biomedical	Building Hope: Genevation's Trailblazing Path to Personalized Cancer Care Prasun Chakraborty , Founder and CEO, Genevation	A Decade of Biosimilars Dracey Poore , MSN, Director of Biosimilars Cardinal Health	Revolutionizing Cancer Care: Bringing Bispecific T-Cell Engagers (BiTEs) to the Community Oncology Frontline Melody Chang , Vice President of Pharmacy Operations, American Oncology Network (Confirmed)	Challenges, Approaches and Considerations in Developing High Concentration MAb Formulations For Patient Self-Administration Aniket Badkar , Director, Formulation and Drug Product Development, Vir Biotechnology (CONFIRMED)
2:40pm	One Format, Many Functions: Diabody-	An Integrated Approach to Managing	Fast-tracking bispecific antibody discovery: A case	CMC Analytical Comparability Strategies for	Strategic Use of Advanced Technologies and	AI-powered data acquisition facilitates the design	Biosafety Testing for Cell and Gene Therapies	Combination Checkpoint Inhibitor Vaccines PD1-Vaxx	The path forward for biosimilars	Navigating the unique challenges for biosimilar	Polysorbate degradation

	<p>Fc-Fab Therapeutics Are On The Way</p> <p>Lauri Peil, Key Account Manager and Technology Officer, Icosagen</p>	<p>Immunogenicity Risk and Optimum Protein Design</p> <p>Emilee Knowlton, Senior Immunology Sales Specialist, ProImmune (CONFIRMED)</p>	<p>study on speeding up workflows with a common light chain platform</p> <p>John Lippincott, Senior Vice President of Therapeutic Discovery Strategies, Alloy Therapeutics</p>	<p>Manufacturing Changes</p> <p>Kevin Zen, Senior Director, IGM Biosciences (CONFIRMED)</p>	<p>Multiple Host Species to Rapidly Generate Cost-Effective Antibody Candidates</p> <p>Vincent Pai, Director, Product Management, Bruker – on behalf of Genovac</p> <p>Iwona Budnicki, Manager, Cellular Immunology, Genovac</p>	<p>of innovative antibodies</p> <p>Tzvika Hartman, SVP Computation, Biolojic Design (CONFIRMED)</p>	<p>Mahdi Roohnikan, Business Development Manager, SGS</p>	<p>in Phase 1 Trial and Preclinical with Emphasis on TIGIT + PD1-Vaxx, PDL1-Vaxx and CTLA-4 Vaxx in Syngeneic Cancer Mouse Models</p> <p>Linlin Guo, Assistant Professor, Indiana University</p>	<p>Craig Burton, Senior Vice President of Policy, Association of Accessible Medicines (Confirmed)</p>	<p>adoption in Specialty Pharmacies</p> <p>Sophia Humphreys, Executive Director, System Pharmacy, Providence Health (Confirmed)</p>	<p>challenges and Risk Mitigation Strategies</p> <p>Sudhakar Voruganti, Director, Business Development, Pfansthiel Inc</p>
3:00pm	<p>Engineering Recombinant Ligand Trap Receptors</p> <p>Rosa Grenha, Director, Protein Science, Keros Therapeutics (CONFIRMED)</p>	<p>From IND to Long Term Commercial Supply: a step ahead against the challenges of the bioconjugates</p> <p>Giorgio Salciarini, Head of Sales – Technical Business Development, BSP Pharmaceuticals</p>	<p>Next Generation Trisppecific T-cell Engagers (TriTCE) Designed to Improve Treatment Responses in Oncology</p> <p>Chayne Piscitelli, Principal Scientist & Group Lead, Zymeworks (CONFIRMED)</p>	<p>Strategies in Early-Stage ADC Discovery & Design for Successful Lead Candidate Development</p> <p>Rob Holgate, VP, Research and Innovation, Abzena</p>	<p>XTEN Polypeptide-Masked Protease Activated T cell engagers: XPAT®[1] proteins - A novel format to mitigate the on-target, off-tumor problem</p> <p>Volker Schellenberger, SVP Research Oncology, Vir Biotechnology (CONFIRMED)</p>	<p>Antibody design using generative artificial intelligence</p> <p>Janani Iyer, Staff Technical Product Manager, Absci</p> <p>Douglas Ganini da Silva, Director Purification, Analytics and CMC & Chief of Staff for Innovation, Absci</p>	<p>Developing New Cancer Immunotherapies: From Bark to Bedside</p> <p>Mark Mamula, Professor of Medicine, Yale</p>	<p>Personalized DNA Neoantigen Vaccine and Pembrolizumab in Advanced Hepatocellular Carcinoma</p> <p>Ildiko Csiki, Chief Medical Officer, Geneos</p>	<p>Achieving a Sustainable Biosimilars Market: The Role of All Stakeholders</p> <p>Barry Chester, Global Commercial Lead – Supportive Care Oncology, Pfizer (Confirmed)</p>	<p>Potential of Biosimilars to Increase Access to Biologics in Emerging Economies</p> <p>Abu Zafor, Deputy General Manager, UniMed UniHealth Pharmaceuticals Ltd.</p>	<p>Single-particle CLiC size-and-payload analysis of mRNA-lipid-nanoparticles with applications to vaccines and genetic medicines</p> <p>Ariadne Tuckmantel Bido, Senior Scientist, ScopeSys (CONFIRMED)</p>
3:20pm	<p>Engineering metalloproteinase inhibitors as potential therapeutic proteins</p> <p>Maryam Raeeszadeh-Sarmazdeh, Assistant Professor, University of Nevada (CONFIRMED)</p>	<p>Re-imagining ADCs: “Preclinical insights into TUB-030 and TUB-040 leveraging Tubulis’ Tubutecan platform”</p> <p>Björn Hock, CDO, Tubulis (CONFIRMED)</p>	<p>EpCAM x CD47 Bi-Specific Antibody Represents a Novel Approach for Treating EpCAM+ Solid Tumors</p> <p>Xiaocheng Chen, Vice President, Antibody Therapeutics, Virtuoso Therapeutics (CONFIRMED)</p>	<p>Potency Assurance for Cellular and Gene Therapy Products</p> <p>Ravish Patel, General Manager-Technical Operation, Kodo Lifescience (CONFIRMED)</p>	<p>Development of a Fully Human CD19 T Cell Engager Using the NonaHCABx Platform</p> <p>Bradley Delaney, Associate Manager, Business Development, Nona Biosciences</p>	<p>Programmable Medicine with Digital Functional Genomics Imaging</p> <p>Jake Chen, Professor, University of Alabama at Birmingham (CONFIRMED)</p>	<p>Panel Discussion: Cell Therapy Regulation</p> <ul style="list-style-type: none"> Omer Butt, VP, Regulatory Affairs, CytImmune Therapeutics Sophia Humphreys, Executive Director, System Pharmacy, Providence Health Kim Walker, Faculty Director, San Diego State University Center for Regulatory Science, College of Sciences <p>Moderator: Chris Mason, Professor, Cell and Gene Therapy, UCL</p>	<p>Potential Breakthroughs in RNA Drug Delivery for Cancer Therapeutics</p> <p>Phong Tran, President and CEO, SirnaMed Therapeutics Inc</p>	<p>Panel: Biosimilar Portfolio Planning & Pipeline Development</p> <ul style="list-style-type: none"> Sandy Yan, Head of US Regulatory Affairs, Shanghai Henlius (Confirmed) Sean McGowan, Vice President, Biosimilars, Amneal Pharmaceuticals (Confirmed) Michael Sarshad, Managing Director, Syneos Health Consulting; Biosimilar Consortium Commercial Lead 	<p>Panel Discussion: Implementing Pro-Biosimilar Decisions</p> <ul style="list-style-type: none"> Implementation in hospitals, cancer centers and employer organizations Payer and formulary decisions Partnerships in biosimilar initiatives <p>David Chen, Director, Drug Use Management, Kaiser Permanente</p> <p>Susan Flaker, SE regional Director of Pharmacy, Mayo Clinic</p>	<p>Fierce rivalry between kinetic stability and thermostability driven degradation pathways in on demand cytokines (ODC). Formulation development case study</p> <p>Pawel Stanczak, Director of Process and Drug Product Development, Tanvex (CONFIRMED)</p> <p>Formulation strategies for highly concentrated biologics</p> <p>Dr. Eddy Berthier, Principal Scientist in Pharmaceutical Development Biologics Drug Products, Lonza</p>
3:40pm	<p>Cis-targeted Immunocytokines: Engineered IL-15 to improve intratumoral T cell function antitumor immunity</p> <p>Javier Chaparro-Riggers, Executive Director, Pfizer (CONFIRMED)</p>	<p>The Selective WEE1 Inhibitor Azenosertib Shows Synergistic Antitumor Effects in Combination With Antibody-Drug Conjugates</p> <p>Joanna Guo, Senior Scientist, Zentalis Pharmaceuticals (CONFIRMED)</p>	<p>CD28-based costimulatory bispecific antibody platform for the treatment of solid tumors</p> <p>Udaya Rangaswamy, Director of Translational Biology, Rondo Therapeutics (CONFIRMED)</p>	<p>Building Robust CMC Assays with Developability in Mind</p> <p>Chris Hepler, Site Head, US-RTP, Solvias AG</p>		<p>Pathomics tools to Map and Quantify TILs in Cancer for Precision Oncology</p> <p>Rajarsi Gupta, Assistant Professor, Stony Brook Medicine</p>		<p>Advancing DNA Medicine: INO-3107 for Recurrent Respiratory Papillomatosis</p> <p>Michael Sumner, Chief Medical Officer, Inovio Pharmaceuticals</p>			

										<p>Shreehas Tambe, CEO & Managing Director, Biocon Biologics</p> <p>Abu Zafor, Assistant General Manager, UniMed UniHealth Pharmaceuticals Ltd.</p> <p>Neelakshi Okhade, Physician, The Permanente Medical Group</p>	
4:00pm	Networking Break Meet the start-ups										
	Protein Engineering THEATER 8	Armed Antibodies THEATER 7	Bispecifics & Multispecifics THEATER 6	CMC & Developability THEATER 5	WORKSHOP KEYNOTE THEATER	AI and Machine Learning for Discovery Combined Antibody-Immunotherapy session THEATER 4	Cell Therapy THEATER 9	Targeting the Tumour Microenvironment THEATER 2	Biosimilar Market Access THEATER 1	Biosimilars in Healthcare Systems THEATER 3	
	Chair: Andrew Tsourkas, Co-Director, Center for Targeted Therapeutics and Translational Nanomedicine; Professor, Bioengineering, University of Pennsylvania	Chair: Philip Arlen, President and Chief Executive Officer, Precision Biologics	Chair: Udaya Rangaswamy, Director of Translational Biology, Rondo Therapeutics	Chair: Savita Nair, Associate Director, CMC Bioassay Analytical Development, Sangamo Therapeutics	Chair: Julio Baez, Industrial Advisor and Consultant Bioprocessing, University of California, San Diego	Chair: Jake Chen, Professor, University of Alabama at Birmingham	Chair: Amitabh Gaur, President, Innovative Assay Solutions LLC	Chair: Pravin Kaumaya, Professor, Indiana University	Chair: Ivo Abraham, Professor of Pharmacy, Medicine and Clinical translational sciences, University of Arizona	Chair: Sophia Humphreys, Executive Director, System Pharmacy, Providence Health	
4:50pm	<p>Phage Displayed Noncanonical Amino Acids to Direct the Search of Potent Ligands for Epigenetic Proteins</p> <p>Trae Hamton, Research Assistant Professor, Texas A&M University (CONFIRMED)</p>	<p>Defining conjugation sites, drug-to-antibody ratios, and ADC proteoforms by multi-level mass spectrometry</p> <p>Kyle Hoffman, Applications Manager, Bioinformatics Solutions</p>	<p>If It Ain't Broke, Keep Trying to Break It: Multispecific Antibody Design to De-Risk Lead Discovery and Drug Development</p> <p>Nicholas Marshall, Head of Protein Sciences, Invenra (CONFIRMED)</p>	<p>Building Strong Bridges: Maximizing the use of expressed drug candidate material to compress timelines and streamline the path to First-in-Human studies</p> <p>Raymond Donninger, Senior Director, Commercial Development, Mammalian, Lonza</p>	<p>Fundamentals of Bioprocessing for Biosimilars</p> <p><i>This workshop is designed for those interested on how biosimilars are developed and manufactured with the following objectives:</i></p> <p>Describe Organisms, Bioreactors and Bioprocesses for scientific, engineering and business professionals with</p>	<p>Affinity by Design – Building Scientific Software Inspired by Natural Antibody Evolution</p> <p>Mary Pitman, Staff Research Scientist, Sandbox AQ (CONFIRMED)</p>	<p>Streamlining multi-modal cell therapy characterization to identify cells with stronger and faster cytotoxicity</p> <p>Shawn Levy, SVP of Scientific Affairs, Cellanome</p>	<p>Preclinical Evaluation of Therapeutic Combinations/ Combination Strategies to Enhance Efficacy of T Cell Engagers for Solid Tumors</p> <p>Anupurna Kaul, Senior Scientist, Amgen</p>	<p>Medicare Drug Price Negotiations and Other Barriers to US Biosimilars</p> <p>Christy Robinson, Principal, MGA</p>	<p>Biosimilars in Healthcare Systems</p> <p>Shreehas Tambe, CEO & Managing Director, Biocon Biologics (Confirmed)</p>	
5:10pm	Engineering novel biologics for the treatment of degenerative retinal diseases: discovery and optimization of	Timeline acceleration – defining and managing a shorter ADC time-to-clinic	Cancer immunotherapy using bispecific gamma delta T cell engagers	Adaptive Formulation Development of biologics and gene therapy modalities		AI and Machine Learning in design, conduct and analysis of Immunotherapy and Antibody Research	Controlling Antibody Affinity to Enhance Immunotherapy Safety and Efficacy	Targeting Tumor Micro-Environment with PD1/IL2 and Other Novel Bispecific Antibodies	Panel Discussion: Lessons Learnt from Humira Biosimilar Adoption & Future Considerations	Fireside Chat: How are Payers adapting to Biosimilars?	

	IGFBPL-1 analogues Christilyn Graff, SVP, Head of Research, Mosaic Biosciences	Sonia Appel, Founder and Principal, Alismere (CONFIRMED)	Hans van der Vliet, CSO, Lava Therapeutics (CONFIRMED)	for pre-clinical and clinical studies Shwetha Iyer, Biotherapeutics Formulation Lab Head, Novartis (CONFIRMED)	some prior biological science experience. Explore Upstream and Downstream Processes development, optimization, control, monitor, and analysis based on Principles behind microbial/cell culture selection, physiology, growth, rDNA technology Separation science principles involved in cell harvesting, chromatography, and filtration.	Jay Mandrekar, Professor Of Biostatistics And Neurology, Mayo Clinic	Yemi Onakunle, Founder and CEO, Mab Switch Inc	Samuel Zhang, Chief Business Officer, Innovent Biologics	<ul style="list-style-type: none"> • Ravish Patel, General Manager- Technical Operation, Kodo Lifescience • Chad Pettit, Executive Director, Executive Director Global Government Affairs, Amgen (Confirmed) • Sean McGowan, Vice President, Biosimilars, Amneal Pharmaceutica ls 	Steve O'Malley, President, Petauri Advisors (Confirmed)	
5:30pm	From Natural Diversity to Synthetic Biology: High Throughput Signal Peptide Engineering to Enhance Protein Biologics Tero-Pekka Alastalo, CEO, Avenue Biosciences (CONFIRMED)	5:30-6:00pm Fireside Chat: Payload and Linker Design Philip Arlen, President and Chief Executive Officer, Precision Biologics Jonas Helma-Smets, CSO and Founder, Tubulis (CONFIRMED)	Speed Counts While Quality Matters: A Fast-Track Approach to Bispecific Antibody Production Gang Liu, Associate Director, Biointron Biological (CONFIRMED)	Host Cell Protein Analytics - Making the Case for Using Advanced Methods to Monitor and Control HCP Alla Zilberman, Vice President, Technical Marketing, Cygnus Technologies		AI in Drug Development Hana Do, Research Analyst, Tufts University	Clinical applications of Stem Cell Derived Secretomes Scott Grealich, Senior Research Scientist, Immunis Inc	Allogeneic immune cell therapy improves drug potency in the tumor micro- environment and patient experience Pamela Contag, CEO, Bioeclipse Therapeutics			
5:50pm	High-Throughput Functional Screening Platforms for Immune-Based Drugs Brandon DeKosky, Associate Professor, Massachusetts Institute of Technology/The Ragon Institute (CONFIRMED)		Structure-Aided Design and Engineering of an FGFR1c x KLB Multispecific Altibody™ Agonist for MASH Yang Shen, Executive Director, Antibody Engineering & Bispecifics, Regeneron (CONFIRMED)	Scalability of GMP Programs and Tools From Early Clinical Stages to Commercial Salome Philip, CMC Project Manager, Attralus (CONFIRMED)	Discuss strategies enabling Accessibility of Biosimilars by optimizing bioprocess performance and costs		The Evolving Landscape of Cell and Gene Therapies: Insights into Current Developments and Future Prospects Aline de Almeida Oliveira, Scientist and Analyst, Competitive Intelligence Office, BIO-MANGUINHOS	Targeted Degradation of Siglec Glyco-Immune Checkpoints to Advance Cancer Immunotherapy Chao Wang, Staff Scientist, The Scripps Research Institute	Moderator: Stan Mehr, Principal, Biosimilars Review & Report (Confirmed)	Oncology Biosimilars: Advancing Care and Overcoming Challenges Clayton Irvine, Senior Manager, oncology cancer Care, Mayo Clinic (Confirmed)	
6:10pm	Onsite drinks reception & poster presentations										

DAY 2

8:00am	Registration opens						
Opening Plenary KEYNOTE THEATER							
09:30am	Chair's opening remarks: Ruchira Das Gupta, Scientific Director, BMS						
09:35am	The Evolving Landscape of Follow-on Biologics: Biosimilars, Biobetters, and Bioparallels Ivo Abraham, Professor of Pharmacy, Medicine and Clinical translational sciences, University of Arizona (Confirmed)						
10:05am	Non-human intelligent agents in early drug discovery and repurposing Tudor Oprea, Professor, University of New Mexico (CONFIRMED)						
10:35am	Networking Break & Showcase Presentations						
	Antibody Roundtables		Immunotherapy Roundtables		Biosimilars Keynotes THEATER 9		
					Chair: Sujay Singh, CEO, Sujan Biologics		
					Chair: Cheryl Marcotte, Senior Director, TA Quality Team Lead, GSK		
					11:30-12:30		
11:30-12:35	TABLE 1 Bispecific antibody engineering: challenges strategies Brandon DeKosky, Associate Professor, Massachusetts Institute of Technology/The Ragon Institute	TABLE 2 Drugging the unreachable: strategies for tissue-specific intracellular delivery	TABLE 9 What is Exciting in Immunotherapy? 1. CAR T Therapy in treatment of solid tumors 2. Antibody Drug Conjugates 3. Checkpoint Inhibitors 4. Bispecific Antibodies 5. Metabolic Modulators for cell therapy Amitabh Gaur, President, Innovative Assay Solutions LLC	TABLE 10 Restructuring the Vaccine Approval Process John Mattison, Operating Partner, Chief Medical Information Officer, Arsenal Capital	11:30-12:00pm From Barriers to Breakthroughs - The Evolving Landscape of Affordable Biologics Sonia T. Oskouei, Vice President & US Head, Biosimilar and Specialty, Sandoz (Confirmed)	11:30-11:50 Title TBA Anuradha Mehta, Sr. Director, Clinical Programs, Early Global Development, AstraZeneca	Building a Better Future: Accelerating the Development of Multi-Use Technologies Developing technologies with multi-use potential (those with commercial and preparedness applications) and enabling technologies provides opportunities for new potential funding mechanisms and strategic partnerships, diverse markets, and a potential path toward sustainability as a company. Unique opportunities exist through public-private partnerships with BARDA in the US Department of Health and Human Services, including BLUE KNIGHT - a joint initiative between Johnson & Johnson & JLABS, to engage earlier and provide resources such as mentorship, to accelerate early-stage companies. For early-stage companies, identifying these potential opportunities can be daunting. During this session, hear from early-stage companies who are navigating this landscape and how they leverage many stakeholder groups to advance their groundbreaking solutions with multi-use potential.
	TABLE 3 Antibody-drug conjugation strategies	TABLE 4 Immunogenicity Considerations Allyson Capili, Scientist, Amgen (CONFIRMED)	TABLE 11 AAV as a Vector for Immunotherapy Jae Sly, Chief Business Officer, Obatala Biosciences	TABLE 12 Building a non-profit organization to advance Treatment Amber Freed, CEO and Founder, SLC6A1	12:00 Biosimilars: promoting value, access, and equity Ivo Abraham, Professor of Pharmacy, Medicine and Clinical translational sciences, University of Arizona (Confirmed)	11:50-12:10 Navigating the Future of Clinical Data Management Aman Thukral, Director, Systems and Digital Operations, Clinical Data Strategy & Operations, Abbvie (Confirmed)	Angela Specht, Global Head, BARDA Alliance, Johnson & Johnson Innovation
	TABLE 5 Implementing AI into antibody discovery and engineering Krishna Allamneni, Chief Development Officer, Concarlo Therapeutics	TABLE 6 Collaboration between academia and industry Jake Chen, Professor, University of Alabama at Birmingham	TABLE 13 Pros and Cons of Immune Checkpoint Inhibition; what's next?	TABLE 14	12:30-1:00pm Towards Advancing the Biosimilar's development pathway (The future of phase III) Mourad Rezk, Vice President-Global Head of Medical and Development (Biosimilars), Biogen (Confirmed)	12:10-12:30 Equity in Clinical Trials Ashley Driscoll-Kani, Associate Director Regulatory Affairs, Intercept pharma	Adrian Guzman, co-founder and CTO, HelioWave Technologies Inc. Spencer Marsh, Chief Scientific Officer, The Tiny Cargo Company Eeshit Dhaval Vaishnav, Founder & CEO, Sequome
	TABLE 7 Analytical and structural characterization of mAbs,	TABLE 8 Beyond mAbs: considerations for				12:30-12:50	Natalija Budimir, Scientific Engagement Lead, Johnson & Johnson Innovation – JLABS

	biosimilars, ADCs, BsAbs, and Fc fusion proteins	developing antibody-like biologics Developing antibody-like biologics, such as bispecific antibodies, ADCs, and nanobodies, presents opportunities to address unmet medical needs beyond traditional mAbs. Through innovative design, engineering, and strategic regulatory approaches, these novel modalities have the potential to revolutionize therapeutic landscapes. Ravish Patel , General Manager- Technical Operation, Kodo Lifescience						How can AI technology make clinical trials more efficient? Amir Emadzadeh , Engineering Director, Genentech (Confirmed)			
12:35pm-1:00pm	<i>Presentations continue in the Biosimilars and Clinical Trials tracks</i>										
12:50	Networking Break Showcase Presentations & Start Up Pitches										
	START-UP PITCHES KEYNOTE THEATER 01:00 PM: SPOC Proteomics Mukilan Mohan, Co-Founder & COO 01:05 PM: Katalyze AI Reza Farahani, CEO 01:10 PM: Aikium , Dr. Eswar Iyer, CEO 01:15 PM: Ontologic , Danielle Orozco Cosio, Co-Founder & CEO 01:20: Med2Bio , Joel Moss & Tonja Phipps, CEO and EVP People & Partnerships 01:25: DefinedBiosence										
	Protein Engineering THEATER 8	mAbs THEATER 7	Analytics, screening and diagnostics THEATER 5	Autoimmune Disorders and Inflammation <i>Combined Antibody-Immunotherapy session</i> THEATER 6	Antibodies for Immunotherapy <i>Combined Antibody-Immunotherapy session</i> KEYNOTE THEATER	Genomics THEATER 9	Finance and Investment for Start Ups THEATER 2	Biosimilar Regulation & Policy THEATER 3	Biosimilar Manufacturing (Development) THEATER 1	Clinical Development THEATER 4	Clinical Operations SHOWCASE THEATER
	Chair: Vibha Jawa , Executive Director, BMS	Chair: Aniket Badkar , Director, Formulation and Drug Product Development, Vir Biotechnology	Chair: Yining Huang , Principal Scientist, Neurocrine Biosciences	Chair: Jingjing Jiang , Senior Director, Development Sciences, Bambusa Therapeutics	Chair: Bruce Keyt , CSO, Multivalent Biosciences	Chair: Shwetha Iyer , Principal scientist II - Lab head, Formulations, Novartis	Chair: Jae Sly , Chief Business Development Officer, Obatala Sciences	Chair: Steven Lehrer , Managing Director, SB Lehrer LLC (Confirmed)	Chair: Julio Baez , Industrial Advisor and Consultant Bioprocessing, University of California, San Diego	Chair: Kim Walker , Faculty Director, San Diego State University Center for Regulatory Science, College of Sciences	Chair:
2:10pm	Accelerating the development of non-classical mAb formats via a novel affinity approach David Wood , Professor, Chemical and Biomolecular Engineering, Ohio State University (CONFIRMED)	Lessons from the SARS Cov2 pandemic; how to be prepared for the future Alessandro Sette , Center Head, Division Head, And Professor, La Jolla Institute (CONFIRMED)	Single-molecule and single-cell microscopy of mRNA-lipid-nanoparticles Sabrina Leslie , Associate Professor, Physics and Astronomy Department, University of British	CUE-401: A Novel IL-2/TGF-beta Fusion Protein for the Induction & Expansion of FOXP3+ Regulatory T Cells Steven Quayle , Vice President & Head of Research Biology and Translational Medicine, Cue Bio	Using In Vitro Tools to Assess the Potential Immune Impact of Biotherapeutic Attributes Allyson Capili , Scientist, Amgen (CONFIRMED)	Genome Sequencing and Genome-wide association study Yi-Hsiang Hsu , Director and associate Professor, Broad Institute of MIT and Harvard	Lilly Gateway Labs: a Novel Incubator Model in Support of the Biotech Ecosystem Kathleen Lin , Site Head, Eli Lilly Gateway Labs	Title TBA Cate Lockhart , Executive Director, Biologics and Biosimilars Collective Intelligence Consortium (Confirmed)	Realising the Biosimilar Investment Thesis Andrew Tedeschi , Vice President, Market Access & Account Management, Organon (Confirmed)	Innovative Design in Clinical Trials Sue Lim , Principal, insight Biologics (Confirmed)	Investigative Site and Patient Receptivity to Direct-to-Patient (DTP) Shipments Madison Ford , Research Analyst, Tufts University

			Colombia (CONFIRMED)								
2:30pm	Engineering Complex Antigens for Biopharma Industry: Multipass Transmembrane Proteins Mary Dwyer, Director, KACTUS	Using Sphere Bio's multi-laser Cyto-Mine Chroma, to accelerate clonal selection during therapeutic development John Lesnick, Senior Field Application Scientist, Sphere Bio	A High-Throughput Validation Approach for Engineered Nanopore Sensors Liviu Movileanu, Professor, Department of Physics, Syracuse University (CONFIRMED)	AI powered drug discovery and development for Autoimmune/Inflammatory diseases June Guo, VP of AI and ML, Athos Therapeutics	Harnessing Protein Engineering to Modulate Immune Responses via CD28 Costimulatory Pathways Michael Hedvat, Director, Discovery Biology, Xencor (CONFIRMED)	Title TBA Bill Paseman, Co-Founder, RareKidneyCancer.org	Pannel Discussion and Q&A <ul style="list-style-type: none">John Mattison, Operating Partner, Chief Medical Information Officer, Arsenal CapitalPascal Krotee, Principal, Rivervest Venture PartnersLeah Villegas, Venture Partner, Aquillius Ventures Moderator: Jae Sly, Chief Business Development Officer, Obatala Sciences	Post-Launch Process Changes: Managing Risk and Ensuring Continuity for an Oncology Product Krishna Allamneni, Chief Development Officer, Concarlo Therapeutics.	Device Selection – The Next Frontier for Biosimilar Development Hillel Cohen, Senior Scientific Advisor, Biosimilars Forum (Confirmed)	US Regulatory Requirements for Clinical Trial Development and Execution Kim Walker, Faculty Director, San Diego State University Center for Regulatory Science, College of Sciences	Methods of assessing participant motivations to clinical trial medication non-adherence Hana Do, Research Analyst, Tufts University (Confirmed)
2:50pm	Engineered cytokine/antibody fusion proteins as novel drugs for cancer immunotherapy Jakub Tomala, Research Assistant Professor, John Hopkins University (CONFIRMED)	Next-Generation Multimeric Human Contraceptive Antibody and Vaginal Delivery Platforms Keiichiro "Kei" Kushiro, Director of Research, Mucommune (CONFIRMED)	Bioanalytical strategies for PK assessment of biologics in preclinical species Srikanth Kotapati, Associate Director, Neurocrine (CONFIRMED)	Title TBA Judy Chou, President and CEO, AltruBio Inc.	OGAP®-Verify: An Enhanced Target Discovery Platform for First in Class ADC and TCE Target Discovery Matthew Metzger, Program, Alliance and Business Manager, Oxford BioTherapeutics (CONFIRMED)	RNAs are not naked Gene Yeo, Professor of Cellular and Molecular Medicine, UCSD		Panel Discussion: Streamlining Biosimilar Development <ul style="list-style-type: none">Wendy Epstein, Professor of Law and Associate Dean of Research and Faculty Development, DePaul University College of Law (Confirmed)Christopher Robertson, Professor of Health Law, Policy & Management, Boston University (Confirmed)Sanjeev Gupta, Sr. Vice President & Head Biosimilar (R&D, Manufacturing and Business Development) Advanced Biotech Lab, Ipca	From Microbial Cultures to Cutting-Edge Biologics: The Evolution of a Fermentation Facility Since 1967 Jeff Rapp, Director of the Bioexpression and Fermentation Facility, University of Georgia (Confirmed)	Overcoming challenges for the clinical study design and execution of allogeneic cell therapies Oscar Segurado, Chief Medical Officer, ASC Therapeutics (Confirmed)	Revolutionizing Clinical Trials: Breaking Barriers with Cutting-Edge Innovation Jyoti Mayadev
3:10pm	Passing USP Particle Requirements is Not Enough - Complete Characterization of Subvisible Aggregates and Impurities in Antibody, Gene, and Cell Therapies using Aura Dikran Khachadourian, Field Application Scientist, Halo Labs	Advancing mAb biomanufacturing: Next-generation innovations Leon Pybus, Associate Director, FUJIFILM Diosynth Biotechnologies	Collision Induced Unfolding: Rapid, Sensitive, Information Rich Stability Measurements for Biotherapeutic Discovery and Development Brandon Ruotolo, Professor, Chemistry, University of Michigan (CONFIRMED)	Panel Discussion: Treating Difficult Targets Jin Lee, Founder, IMIDEology Shanelle Gabriel, Patient and Advocate Shamekka Marty, Patient and Advocate		Advancing Novel Platform MOA and Cutting-Edge Vector Technology to treat Neurological Disorders and Chronic Pain Roelof Rongen, CEO, Adolare BioTherapeutics			HyperXpress™ Biomanufacturing: A Paradigm Shift in Plant-Based mAb Biosimilar Production Jeroen Hofenk, Co-Founder and CSO, SwiftPharma (Confirmed)	Panel Discussion: Putting Patients Front and Center Medicine is becoming patient centric, which requires educating patients about their choices once they are past "Standard of Care". This session will discuss how we can better educate these patients about those choices: including personalized medicine, clinical trials and off-label drug usage. <ul style="list-style-type: none">William Paseman, founder, Rare Kidney Cancer (Confirmed)	What Do We Mean by Interoperability for Quality Data? Samina Qureshi, International Medical Officer, MedDRA MSSO (Confirmed)
3:30pm	Strategies to Enable Antibody Discovery and Characterization for Complex Targets Keenan Taylor, Principal Scientist I, AbbVie (CONFIRMED)	Validation of Structural-Based Machine Learning Designed In Vitro Libraries Sam Stimple, Senior Director Antibody Engineering, Twist Biosciences				Genomics The foundation for RNA targeted therapies Brenda Baker, Executive Director, Ionis Pharmaceuticals					Accelerating Clinical Trial Timelines: The Vital Role of Primary Care Pete Fronte, President / CEO, Altura

								<p>Laboratories</p> <ul style="list-style-type: none"> Sarfaraz Ni azi, Professor, University of Illinois <p>Moderator: Sue Lim, Principal, insight Biologics</p>		<ul style="list-style-type: none"> Zoran Kronic, Senior Manager Data Science, R&D, Amgen (Confirmed) Ezra Cohen, Co-Director of the Center for Engineering in Cancer, Professor of Medicine, UC San Diego (Reserved) Amber Freed, CEO and Founder, SLC6A1 	
3:50pm	Networking Break										
	Protein Engineering THEATER 8	mAbs THEATER 7	Immunogenicity & QA/QC THEATER 2	Autoimmune Disorders and Inflammation <i>Combined Antibody-Immunotherapy session</i> THEATER 6	Proteomics & Mass Spectrometry THEATER 5	Gene Therapy THEATER 9	Biomarkers Precision Medicine and Companion Diagnostics KEYNOTE THEATER	Biosimilar Regulation & Policy THEATER 3	Biosimilar Manufacturing (Characterization & Analysis) THEATER 1	Translational Medicine THEATER 4	AI and Data in Clinical Trials SHOWCASE THEATER
	Chair: David Wood, Professor, Chemical and Biomolecular Engineering, Ohio State University	Chair: Jakub Tomala, Research Assistant Professor, John Hopkins University	Chair: Allyson Capili, Scientist, Amgen	Chair: Shanelle Gabriel, Patient and Advocate	Chair: Brandon Ruotolo, Professor, Chemistry, University of Michigan	Chair: Sophia Humphreys, Executive Director, System Pharmacy, Providence Health	Chair: Prasun Chakraborty, CEO and Founder, Genevation	Chair: Giuseppe Randazzo, Biosimilar Education, AAM	Chair: Julio Baez, Industrial Advisor and Consultant Bioprocessing, University of California, San Diego	Chair: Rajarsi Gupta, Assistant Professor, Stony Brook Medicine	Chair: Jay Mandrekar, Professor Of Biostatistics And Neurology, Mayo Clinic
4:30pm	Engineering Next-Generation Biologics with High-Resolution Protein-Protein Interaction Data and Machine Learning Davis Goodnight, Senior Scientist, A-Alpha Bio (CONFIRMED)	Inducing passive immunity to HIV with monoclonal antibodies Huub Gelderblom, Director of Strategic Partnerships, Fred Hutchinson Cancer Center (CONFIRMED)	Novel Preclinical Immunogenicity Assessment Approaches for New Modalities Vibha Jawa, Executive Director, BMS (CONFIRMED)	BBT001: A Novel Tetravalent Bispecific Antibody Targeting IL-4R α and IL-31 for Enhanced Atopic Dermatitis Therapy Jingjing Jiang, Senior Director, Development Sciences, Bambusa Therapeutics	Multi-proteomic profiling of a CHO model system of lactate overproduction reveals insight into metabolic dysfunction during bioproduction Joshua Justice, Proteomics Scientist, Johnson & Johnson (CONFIRMED)	Characterization of Viral Vector Proteins for Gene Therapy Development Yu Zhou, Manager, Analytical Development, Millipore Sigma	Toward a Blood-Based Biomarker for Early Detection of Alzheimer's Disease Sheng Zhong, Professor, UCSD	Law and Ethics of Providing Access to Drugs Before FDA Approval Christopher Robertson, Professor of Health Law, Policy & Management, Boston University (Confirmed)	Adopting the best practices for achieving highest titer and best match for mAb Biosimilar Sanjeev Gupta, Sr. Vice President & Head Biosimilar (R&D, Manufacturing and Business Development) Advanced Biotech	Bridging Clinical Translatability for Target Discovery and Precision oncology through a human centric R&D paradigm Xi Zhao, Head, Oncology Bioinformatics, Research and Development, Abbvie (CONFIRMED)	Clinical Trials in the AI Age: Quantum Computing and Beyond Zoran Kronic, Senior Manager Data Science, R&D, Amgen (Confirmed)

									Lab, Ipca Laboratories		
4:50pm	<p>From Gene to Drug: Enhancing Drug Discovery with Recombinant Target Protein Strategies</p> <p>Isabelle Lehoux, Director, Protein Biochemistry, Gilead (CONFIRMED)</p>	<p>Targeting of respiratory infections with novel antibody formats</p> <p>Sam Lai, Professor, Division of Pharmacoengineering and Molecular Pharmacetics, UNC Chapel Hill (CONFIRMED)</p>	<p>Regulatory-Compliant Strategies for Timely and Cost-Effective Immunogenicity Risk Assessment and Mitigation</p> <p>Adeleh Taghi Khani, Senior Scientist II, Quest Diagnostics (CONFIRMED)</p>	<p>From Discovery to Clinic: Immunogenicity Risk Assessment in Autoimmune Disease Biologics</p> <p>Yinyin Li, Principal Scientist, Genentech (CONFIRMED)</p>	<p>Immunopeptidomics applications in drug development: immunogenicity risk assessment & peptide profiling for pharmacodynamics</p> <p>Arun Tailor, Principal Scientist – Drug Development, Genentech (CONFIRMED)</p>	<p>Raw Materials in Gene Therapy: Start Right Early in Process Development</p> <p>Ravish Patel, General Manager-Technical Operations, Kodo Life Sciences</p>	<p>Using Real World Evidence and Biological Predictors to Improve Health Outcomes</p> <p>Amrita Basy, Associate Professor, UCSF</p>	<p>Ensuring the Quality of Biologics and Biosimilars</p> <p>Fouad Atouf, Senior Vice President, United States Pharmacopeia</p>	<p>Optimizing biotherapeutic glycosylation through genome editing, systems biology, and A.I</p> <p>Nathan Lewis, Professor, University of Georgia (Confirmed)</p>	<p>Epigenetic modulation enhances adoptive T cell immunotherapy against multiple cancer models</p> <p>Patrizia Porazzi, Senior Research Investigator, Haematology and Oncology, University of Pennsylvania</p>	<p>The Role of AI and Data Analytics in Transforming Clinical Trials and Medical Research</p> <p>Jay Mandrekar, Professor of Biostatistics and Neurology, Mayo Clinic (Confirmed)</p>
5:10pm	<p>Anti-CD3 screening: Bispecific antibody assembly workflow using controlled Fab-arm Exchange</p> <p>David Grandy, Senior Scientist, Merck (CONFIRMED)</p>	<p>Enhanced Antibody Effector Function Through Glycoengineering</p> <p>Qiang (Shawn) Chen, Professor, Arizona State University (CONFIRMED)</p>	<p>Development of Nonclinical Total ADA Assays for Immunogenicity Assessment of a New Therapeutic Modality in Toxicology Studies</p> <p>Audrey Arjomandi, Senior Principal Scientist, Genentech (CONFIRMED)</p>	<p>Bi-directional antibodies for treating auto-immune disease</p> <p>Jyothsna Visweswaraiah, Director, Biotherapeutics, Drug Creation, Seismic Therapeutic (CONFIRMED)</p>	<p>Revolutionizing ADCs: Advanced Synthesis and Characterization of Trastuzumab MMAE Conjugates</p> <p>Steven Calciano, Business Development Manager, SCIEX</p>	<p>Coming to Terms with Car-T: Contracting for Car T</p> <p>Susan Flaker, SE regional Director of Pharmacy, Mayo Clinic</p>	<p>A Focus on Digital Pathology & AI Approaches in Companion Diagnostics & Biomarkers</p> <p>Anupam Aich, Product Definition Lead, Roche</p>	<p>High-Need Biologics and Optimizing Innovation</p> <p>Wendy Epstein, Professor of Law and Associate Dean of Research and Faculty Development, DePaul University College of Law</p>		<p>Fighting Like a Mother</p> <p>Amber Freed, CEO and Founder, SLC6A1</p>	<p>Risk Based Quality Management Revealed In Clinical Trials: A Decade of Discovery & the Blueprint for Tomorrow's Breakthroughs</p> <p>Sathya Ramnath, Senior manager for Risk Based Quality Management, Gilead</p>
5:30pm	<p>Innovative strategies for neutralizing viral entry and application to future pandemics</p> <p>Andrew DiChiara, Senior Scientist II, Abbvie (CONFIRMED)</p>	<p>Antibody Therapy Strategy to Alter Solid-Tumor Micro-Environment for Dramatic Increase of Chemotherapy Efficacy</p> <p>Roelof Rongen, Co-Founder & Board Member, Stealth</p>		<p>XmAb657 and Plamotamab: Advancing CD19 and CD20 Bispecific T-Cell Engagers for Autoimmune Disease Therapy</p> <p>Matthew Bernett, Executive Director, Protein Engineering, Xencor (CONFIRMED)</p>	<p>Quantitative Target Engagement for a KRAS G12C Inhibitor in FFPE Tumor Tissues using IA 2D-LC-MS/MS</p> <p>Aiying Yu, Senior Scientist, Genentech (CONFIRMED)</p>	<p>Gene Therapy for Genetic Cardiac Disease</p> <p>Jing Zhang, Laboratory head, University of California San Diego</p>	<p>CDx in Motion: Where Are U.S. and EU Regulators Headed?</p> <p>Karin Hughes, SVP, Beaufort</p>	<p>The Final Stage of Biosimilars Era: Turning into Biogenerics</p> <p>Sarfaraz Niazi, Professor, University of Illinois</p>		<p>Title TBA</p> <p>Marianne Hamilton Lopez, Senior Research Director, Biomedical Innovation, Duke-Margolis Center for Health Policy</p> <p><i>(Confirmed)</i></p>	
5:50pm	<p>Toward enhancement of antibody thermostability and affinity by computational design in the absence of antigen</p> <p>Net Haskins, Scientist II, Protein Engineering, Amgen (CONFIRMED)</p>	<p>Title TBA</p> <p>Ankit Mahendra, Senior Principal Scientist, Lab Head, Antibody Platform, Sanofi (CONFIRMED)</p>		<p>Antibody treatments for fibrosis</p> <p>Yue Zhao, Principal Scientist, Genentech (CONFIRMED)</p>		<p>Gene Therapy for Parkinson's Disease</p> <p>Marshall Goodwin, Principal Scientist, NYSNObio</p>		<p>Navigating the Regulatory Landscape of Biosimilars: Challenges, Strategies, and Future Perspectives</p> <p>Hetal Patel, Vice President, Medical Affairs, Celltrion Healthcare (Confirmed)</p>			
6:10pm	Conference Close										

