PHILLY
Advanced Cell and Gene Therapy in Philadelphia

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2024 @PHILLY CELL AND GENE THERAPY ANNUAL CONFERENCE

This meeting brings together the innovators and business leaders to foster collaborations and advance cell and gene therapy in the Greater Philadelphia area

14-15 June, 2024

Sheraton Valley Forge Hotel, 480 N Gulph Rd, King of Prussia, PA 19406

Business: The Business of Saving Lives Partner THE CHAMBER of Commerce for Greater Philadelphia

Scientific Track - Gene Therapy, CMC, Cell Therapy, RNA, Clinical/Regulatory

A WELCOME LETTER FROM CONFERENCE CO-CHAIRS

Dear Esteemed Guests and Colleagues,

Welcome to the SAPA-GP @Philly Cell and Gene Therapy Conference 2024! We are thrilled to host you in the vibrant suburbs of Philadelphia for this pivotal event in the field of cell and gene therapy.

Our mission at SAPA-GP is to foster knowledge exchange, professional growth, and networking opportunities for professionals across the pharmaceutical and biotechnology sectors. This year's conference builds upon the success of our inaugural event and promises to be a landmark gathering featuring a series of expert-led sessions, panel discussions, and networking opportunities designed to drive forward the field of cell and gene therapy. We are honored to have distinguished speakers, who will share expert insights and outlook for the industry.

The past year has seen remarkable progress in cell and gene therapy. FDA approvals for groundbreaking therapies have soared, with notable examples such as Sarepta Therapeutics' gene therapy for Duchenne muscular dystrophy and BioMarin Pharmaceutical's Roctavian for hemophilia A. These approvals underscore the transformative potential of genetic disorder treatment.

Furthermore, the global cell and gene therapy market is experiencing unprecedented growth, with projections indicating a market value of $13.8 billion by 2027, driven by a compound annual growth rate (CAGR) of 33.6%.

Advances in CRISPR technology, next-generation sequencing, and manufacturing processes are revolutionizing the field. Intellia Therapeutics' in vivo CRISPR-based therapy, NTLA-2001, has demonstrated significant reductions in transthyretin protein levels in patients with transthyretin amyloidosis, marking a pivotal achievement in gene-editing therapies.

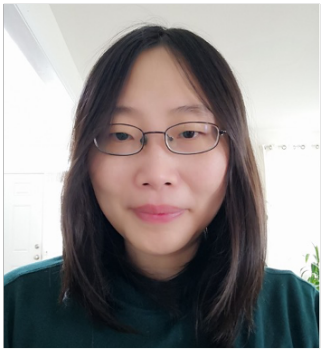
SAPA-GP is committed to supporting the growth of cell and gene therapy through initiatives like our conference. We hope you find this event informative and inspiring, and we look forward to engaging discussions and collaborations.

We extend our heartfelt gratitude to the meeting organizers, sponsors, volunteers, and all individuals who have contributed their time, effort, and resources to make this conference possible. Your dedication and support are deeply appreciated.

Thank you for joining us in Philadelphia, and we wish you a productive and enjoyable conference.

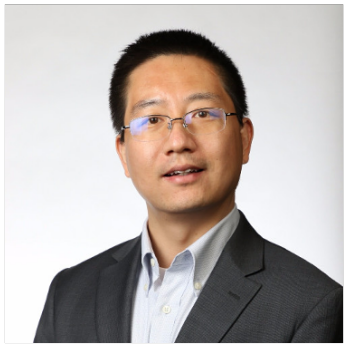
Sincerely,

SAPA-GP President Office



Lu Wang, Ph.D., M.B.A.,
President-elect of SAPA-GP 2025-26;
Conference Chair

Yang Yuan, Ph.D.,
Immediate Past President SAPA-GP 2023-24;
Conference Co-Chair



Yufeng Li, Ph.D.,
President of SAPA-GP 2024-25;
Conference Co-Chair

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2024 @Philly CGT Annual Conference Program-At-A-Glance

DAY1 June 14, 2024

8:45 A.M.	Keynote Speech: Peter Marks, M.D., Ph.D., Director, Center for Biologics Evaluation and Research, FDA				
9:45 A.M.	Coffee Break & Networking				
	Gene Therapy	**Chemistry, Manufacturing and Controls**	**Business Track-1**	**Business Track-2**	**Company Showcase**
10:05 A.M.	Session 1: Navigating the Challenges in Gene Therapy	Session 1: Standing on the Shoulder of Giants: Current CMC Strategy and Future Development Trends	Session 1: Maximizing Economic Incentives in Greater Philadelphia to Grow Biotech Startups	Session 1: Intellectual Property Protection and Licensing Strategies for Cell and Gene Therapy Companies	Networking
11:35 A.M.	Lunch Break and Networking/Company Sponsored Lunch Sessions - CIC Labs+Innovation Campus (11:45 a.m.-12:45 p.m.)				
12:45 P.M.	Keynote Speech: Jason Bock, Ph.D., CEO, Cell Therapy Manufacturing Center				
1:40 P.M.	Coffee Break & Networking				
2:00 P.M.	Session 2: From Rare to Common: Exploring the Evolution of Gene Therapy in Disease Treatment	Session 2: From Source to Product: Advance Quality Control for CGT Manufacturing	Session 2: Hidden Traps: What Makes Investors Walk Away from Your Pitch?	Session 2: Navigating Talent Partnerships and Project Management	Company Showcase: Qiagen
3:30 P.M.	Coffee Break & Networking				
3:45 P.M.	Session 3: The Future of Gene Therapy: Exploring Cutting-Edge Techniques and Boundless Potential	Session 3: From Process to Consequence: Enhancing Quality Assurance for Production Readiness and Approval	Session 3: From Fundraising to Exit: How to Build a Startup's Legal Armor	Session 3: Digitization of GMP Documentation: Operational Impact & Lessons Learned	Networking
5:15 P.M.	Reception				
6:00 P.M.					
8:00 P.M.	Dinner				

2024 @Philly CGT Annual Conference Program-At-A-Glance

DAY2 Jun 15, 2024

8:45 A.M.	Keynote Speech: Guangping Gao, Ph.D., Professor and Director, Horae Gene Therapy Center, UMass Chan Medical School			
9:35 A.M.	Keynote Speech: PJ Brooks, Ph.D., Deputy Director, Division of Rare Diseases Research Innovation National Center for Advancing Translational Sciences National Institutes of Health			
10:20 A.M.	Coffee Break & Networking			
	Cell Therapy	**Clinical Development and Regulatory**	**RNA and Gene Editing**	**Business**
10:40 A.M.	Session 1: Innovative Cell Therapy beyond CAR-T	Session 1: Unique Challenges of Clinical Development for Gene Therapy	Session 1: The Next-Gen CRISPR and the Future of Gene Editing	Session 1: Using Strategic Partnerships, Licensing, and Venture Financing to Get to Your Next Critical Value Inflection Point
12:10 P.M.	Lunch Break and Networking / Company Sponsored Lunch Sessions-AAVnerGene, Finnegan Henderson, uBriGene (12:25-1:25 p.m.)			
1:30 P.M.	Session 2: Current Understanding and Management of Toxicities for Cell Therapy	Session 2: Clinical & Regulatory Considerations for Cell Therapy in Hematology & Oncology	Session 2: Bioanalytical, DMPK and Clinical Pharmacology Strategies for In Vivo Characterization of Nucleic Acid Therapy	Session 2: From the Bench to the Board Room: Navigating the World of Entrepreneurship, Innovation and Corporate Venture Capital in the Biotech Industry
3:00 P.M.	Coffee Break & Networking			
3:15 P.M.	Networking	Session 3: TBD	Networking	Session 3: Talk-To-An-Investor
4:45 P.M.	Reception			
5:45 P.M.				

AGENDA Friday, June 14th, 8:00 a.m.-5:15 p.m.

8:00-8:45 a.m.	Check in

Plenary Session	**Grand Ballroom**
8:45-9:00 a.m.	**Opening Remarks:** Yufeng Li, Ph.D., President SAPA-GP 2024-25; Conference Co-Chair; Director, Clinical Scientist, Vivace
9:00-9:45 a.m.	**Keynote speech: Advancing the Development of Novel Biologic Products** Peter Marks, M.D., Ph.D., Director, Center for Biologics Evaluation and Research, FDA
9:45-10:05 a.m.	**Coffee Break and Networking**

10:05-11:35 a.m. Parallel Sessions

Gene Therapy	**Grand Ballroom**
Session 1: Navigating the Challenges in Gene Therapy	
Session chair:	Lili Wang, Ph.D., Research Associate Professor Emeritus, Gene Therapy Program, University of Pennsylvania
10:05-10:35 a.m.	**Immunogenicity to AAV Gene Therapy - Challenges and Advancements** Renuka Pillutla, Ph.D., SVP, Head of Development Sciences, Spark Therapeutics
10:35-11:05 a.m.	**Integrated AAV Vector Genomes and the Future of Liver Gene Therapy** Jenny Greig, Ph.D., Executive Director of Gene Therapy Program, University of Pennsylvania
11:05-11:35 a.m.	**Regulatory Considerations for Gene Therapy Development** Sonali Patel, Pharm.D., Director of Regulatory Affairs, Spark Therapeutics

Chemistry, Manufacturing and Controls (CMC)	**Centennial 1**
Session 1: Standing on the Shoulder of Giants: Current CMC Strategy and Future Development Trends	
Session chair:	Huize Yan, M.S., Process Development Scientist, Spark Therapeutics
10:05-10:10 a.m.	**Track Lead Opening**
10:10-10:40 a.m.	**Leveraging the Power of an iPSC Platform to Produce NK and T Cells at Low Cost and High Volume** Gregory Russotti, Ph.D., CTO & CMO, Century Therapeutics

10:40-11:10 a.m.	**Navigating the Challenges in Gene Therapy: Gene Therapy Overview, Challenges, and Future Prospective** Kenneth Gene Yancey, Ph.D., Executive Director, Process Development & Manufacturing, Gene Therapy Program, University of Pennsylvania
11:10-11:35 a.m.	**Panel Discussion** Morning speakers

Business Track-1 — Centennial 2

Session 1: Maximizing Economic Incentives in Greater Philadelphia to Grow Biotech Startups

Session chair:	Bryan Tsao, Ph.D., Manager, Life Science & Healthcare Initiatives, Chamber of Commerce for Greater Philadelphia
10:05-11:35 a.m.	**Panel Discussion and Q&A** Panelists: • Melina Blees, Ph.D., Site Head, BioLabs Philadelphia • Rebecca Grant, DVM, Sr. Director, Life Sciences & Biotechnology Philadelphia Department of Commerce • Ian McLaughlin, Ph.D., VP of Government Affairs, BioNJ • Noah Olson, M.B.A., Director of Innovation, Delaware Prosperity Partnership

Business Track-2 — Centennial 3

Session 1: Intellectual Property Protection and Licensing Strategies for Cell and Gene Therapy Companies

Session chair:	Steve Jannetta, Partners, Morgan Lewis, Philadelphia Office
10:05-11:35 a.m.	Panelists: • Lou Beardell, Partner, Morgan Lewis. Philadelphia Office • Laurie Burlingame, Partner, Morgan Lewis. Boston Office • Maurits Geerlings, President and CEO Nanocell Therapeutics, Inc. • Andrew Haupt, Partner, Morgan Lewis. Philadelphia Office

11:35 a.m.-12:45 p.m. — **Lunch Break and Networking**

Lunchtime Session: CIC Lab+Innovation Campus — Malvern Room

Session host	Patricia Tsao, COO and Scientific Director, CytoEX Inc.
11:45 a.m.-12:45 p.m.	**The Importance of a Shared Community for Starting & Building Your Life Science Company** Kelly Sullivan, Ph.D., Director of Labs, CIC Lab+ Innovation Campus

Plenary Session	Grand Ballroom
12:45-12:55 p.m.	**Opening Remarks:** Lu Wang, Ph.D., M.B.A., President-elect SAPA-GP; Conference Chair; Director, Downstream Development, Spark Therapeutics Jin Wen, Ph.D., Sr. Scientist, Analytical Development, Spark Therapeutics
12:55-1:40 p.m.	**Keynote Speech: Accelerating the Cell Therapy Transformation** Jason Bock, Ph.D., CEO, Cell Therapy Manufacturing Center
1:40-2:00 p.m.	**Coffee Break and Networking**

2:00-3:30 p.m. Parallel Sessions

Gene Therapy	Centennial 1
Session 2: From Rare to Common: Exploring the Evolution of Gene Therapy in Disease Treatment	
Session chair:	Jingwen Niu, Ph.D., Principal Investigator, AlphaThera
2:00-2:30 p.m.	**Gene Therapy Targets for Diseases of the Visual System** Gareth Thomas, Ph.D., Associate Professor, Temple University Lewis Katz School of Medicine
2:30-3:00 p.m.	**Evolving Gene Therapy for Common Neurological Diseases** Lingzhi Zhao, Ph.D., VP, NeuShen Therapeutics
3:00-3:30 p.m.	**Panel Discussion** Session 2 speakers

Chemistry, Manufacturing and Controls (CMC)	Grand Ballroom
Session 2: From Source to Product: Advance Quality Control for CGT Manufacturing	
Session chair:	Yu-Chih Hsu, Ph.D., Director of Bioassay Development and QC, Gene Therapy Program, University of Pennsylvania
2:00-2:30 p.m.	**Spark Therapeutics Quality Control Strategies for: Reference Standard, External Partner Management & Operational Excellence** Tonya Hutchison, M.B.A, Sr. Director, Quality Control Operations, Spark Therapeutics
2:30-3:00 p.m.	**Plasmids Sequence Purity and Analytical Considerations for rAAV Products**

Amy Gallagher, B.S., Principal Scientist Analytical & Quality Control, Spark Therapeutics

3:00-3:30 p.m. **AAVone: One Plasmid AAV Production System Solves AAV Manufacture Bottleneck Problems**

Daozhan Yu, Ph.D., President and CEO, AAVnerGene

Business Track-1 — Centennial 2

Session 2: Hidden Traps: What Makes Investors Walk Away from Your Pitch?

Session chair: Michele Washko, M.B.A., M.A., President & CEO, Life Sciences Greenhouse Investments

2:00-3:30 p.m. **Panel Discussion and Q&A**

Panelists:

- Jason Butler, Ph.D., Managing Director, Director of Healthcare Research, Citizens JMP
- David Kellman, BSE., Managing Director, Head of Healthcare Investment Banking, Citizens JMP
- Patrick Lundgren, Ph.D., Investor, Hummingbird Ventures
- Vikram Patra, M.B.A., Managing Director, Freedom Capital Markets
- Enna Weng, M.B.A., Managing Director, Freedom Capital Markets
- Brian Zhou, Ph.D., Associate Director, Lily Venture, Eli Lilly and Company

Business Track-2 — Centennial 3

Session 2a: Navigating Talent Partnerships: Optimizing HR Outsourcing in the Evolving Cell & Gene Therapy Sector

Session chair: Marcia Zaruba O'Connor, M.S., Founder and CEO, The O'Connor Group

2:00-3:30 p.m. **Panel Discussion and Q&A**

- Meghan Popoleo, VP of Growth, The O'Connor Group
- Kim Bunting, Director of the Human Capital Consulting Practice, The O'Connor Group

Business Track-2 — Malvern

Session 2b: Strategic Value Creation -Where Biotechnology Businesses Meet Project Management!!

Session chair: TBD

2:00-3:00 p.m. Leena Pattarkine, Ph.D., Program Lead Biotechnology, Director Capital Area Biotechnology Partnership, Harrisburg University of Science and Technology

Company Showcase — Haverford Room

Company Showcase: Qiagen

Session chair: Xinjun Zhang, Ph.D., Associate Principal Scientist, Merck

2:00-3:30 p.m. **Analysis of DNA Integrity and Stability Using Digital PCR -A Rapid Approach for Characterizing AAV Genome Integrity**
Samir Afif, Ph.D., Sr. Account Manager Life Science, North America, Qiagen

3:30-3:45 p.m. **Coffee Break and Networking**

3:45-5:15 p.m. Parallel Sessions

Gene Therapy — Centennial 1

Session 3: The Future of Gene Therapy: Exploring Cutting-Edge Techniques and Boundless Potential

Session chair: CJ (Chunjuan) Song, Ph.D., VP, ExegenesisBio

3:45-4:15 p.m. **Multiomic Sequencing in Characterization, Safety, and Quality Control of in vivo and ex vivo Cell and Gene Therapies**
Kirsten Copren, Ph.D., Director, Analytical Development, National Resilience, Inc.

4:15-4:45 p.m. **AI-driven Decision Making for Gene Therapy**
Irene Rombel, Ph.D., M.B.A., CEO, President and Co-Founder, BioCurie

4:45-5:15 p.m. **Modified AAV5 Vectors: From Underperformer to Top Performer**
Bin Xiao, Ph.D., M.D., Director of R&D, Askbio. Inc.

Chemistry, Manufacturing and Controls (CMC) — Grand Ballroom

Session 3: From Process to Consequence: Enhancing Quality Assurance for Production Readiness and Approval

Session chair: Long Geng, Ph.D., Sr. Scientist, Clinical Biomarker

3:45-4:15 p.m. **Moving from Research Concept to Tangible Cell Therapy Asset for Clinical Evaluation: Critical CMC Learnings**
Shyam Subramanian, Ph.D., Principal, Biosynth Solutions

4:15-4:45 p.m. **Overview and Progress of CAR-T Cell Therapy Manufacturing Development**
Kaiyuan Jiang, Ph.D., Associate Director, Cell Therapy Process Development, Johnson & Johnson Innovative Medicine

4:45-5:15 p.m. **Panel Discussion**
Panelists: Afternoon speakers

Business Track-1	Centennial 2

Session 3: From Fundraising to Exit: How to Build a Startup's Legal Armor

Session chair: Sima Kulkarni, J.D., M.S., Special Counsel, Duane Morris LLP

3:45-5:15 p.m. **Panel Discussion**

Panelists:

- Rebecca Guzman, J.D., Partner, Vice Chair of M&A Division, Duane Morris LLP
- Wendy Pan, Ph.D., J.D., Partner, Goodwin Procter LLP
- Aliya Sanders, J.D., M.P.H., Partner, Gunderson Dettmer

Business Track-2	Centennial 3

Session 3: Digitization of GMP Documentation: Operational Impact & Lessons Learned

Session chair: Matt Cabrey, Director, Ideas x Innovation Network (i2n)

3:45-5:15 p.m.

Panelists:

- Patrick Denninger, CEO, CellPort Software
- Robert Steinhagen, VP, Life Sciences Division, ABM Industries

5:15-6:00 p.m.	**Reception**
6:00-8:00 p.m.	**Dinner** (Invitation Only)
Appreciation Speech	**Yufeng Li, Ph.D., SAPA-GP president (2024-25)**

AGENDA Saturday, June 15th, 8:00 a.m.-5:45 p.m.

8:00-8:45 a.m.	Check in
Plenary Session	**Grand Ballroom**
8:45-8:50 a.m.	**Opening Remarks:** Haichen Yang, M.D., M.B.A. Former President SAPA-GP 2022-23; Conference Advisory Committee Co-chair; VP, Clinical Research, Amicus Therapeutics
8:50-9:35 a.m.	**Keynote speech: AAV Gene Tx for CNS Disorders** Guangping Gao, Ph.D., Professor and Director, Horae Gene Therapy Center, UMass Chan Medical School
9:35-10:20 a.m.	**Keynote speech: Beyond "One Disease at a Time": Towards Therapeutic Platforms for the Treatment of Rare Monogenic Disease** PJ Brooks, Ph.D., Deputy Director, Division of Rare Diseases Research Innovation National Center for Advancing Translational Sciences National Institutes of Health
10:20-10:40 a.m.	**Coffee Break and Networking**

10:40 a.m. -12:10 p.m. Parallel Sessions

Cell Therapy	**Grand Ballroom**
Session 1: Innovative Cell Therapy beyond CAR-T	
Session chair:	Shuai Dong, Ph.D., Sr. Manager, Quantitative Clinical Pharmacology, Sarepta Therapeutics
10:40-11:10 a.m.	**TIL Immunotherapy for Solid Tumors** Hequn Yin, Ph.D., SVP & Head of Research, Iovance Biotherapeutics
11:10-11:40 a.m.	**Discovery of a Multi-Engineered iPSC-Derived Cell Therapy Product** Michael Naso, Ph.D., SVP, Century Therapeutics
11:40 a.m.-12:10 p.m.	**The Progress and Challenge of Cell Therapy Targeting CNS Diseases** Jing Fan, Ph.D., Founder, President & CEO, Hopstem Bio
Clinical Development and Regulatory	**Centennial 1**
Session 1: Unique Challenges of Clinical Development for Gene Therapy	
Session chair:	Mitra Tavakkoli, M.D., Pharm.D., Independent Sr. Clinical Consultant

10:40-11:10 a.m.	**Data-Sharing to Improve Safety and Efficiency in Gene Therapy Clinical Development** Genevieve (Jenny) Laforet, M.D., Ph.D., SVP, Clinical Development, Aspa Therapeutics/BridgeBio Gene Therapy
11:10-11:40 a.m.	**Placebo Control Arms in Rare Disease Clinical Trials: Main Considerations** Mitra Tavakkoli, M.D., Pharm.D, Independent Sr. Clinical Consultant
11:40 a.m.-12:10 p.m.	**Imlifidase as a Pre-treatment to Enable AAV based Gene Therapy in Patients with Antibodies Towards the Vector** Lena Winstedt, Ph.D., Global Franchise Lead Gene Therapy, Hansa Biopharma AB

RNA and Gene Editing Therapy — Centennial 3

Session 1: The Next-Gen CRISPR and the Future of Gene Editing

Session chair:	Tao Niu, Ph.D., Director, Quantitative Clinical Pharmacology, Sarepta Therapeutics
10:40-11:10 a.m.	**Next-Generation CRISPR Gene-Editing Technology for Drug Development** Alvin Luk, Ph.D., MBA., CCRA, Co-founder and CEO, HuidaGene
11:10-11:40 a.m.	**An Innovative Technology for High Yield and More Stable CRISPR Guide RNA** Xiulian Sun, Ph.D., CTO, uBriGene
11:40 a.m.-12:10 p.m.	**Transform DMD through Base Editing Technology** Chunyan He, Ph.D., CEO, Suzhou GenAssist Therapeutic

Business — Centennial 2

Session 1: Using Strategic Partnerships, Licensing, and Venture Financing to Get to Your Next Critical Value Inflection Point

Session chair:	Lisa Baskin, B.S., SVP of Scientific Real Estate, Scheer Partners
10:40 a.m.-12:10 p.m.	Panelists: • Hugh Davis, Ph.D., CB&DO, President, Biosion USA, Inc. • Sean Fu, Ph.D., M.B.A., Operating Partner, ABio-X • Sunil Joshi, M.B.A., M.S., President, Strategius Consultants • Marian Nakada, Ph.D., VP of Venture Investments J&J Innovation-JJDC

- Heather Rose, Ph.D., J.D., VP of Technology Licensing and Start-ups, Thomas Jefferson University & Jefferson Health

12:10-1:30 p.m.	**Lunch Break and Networking**
Lunchtime Session: AAVnerGene	**Malvern Room**
Session host	Ying Zhou, Ph.D., M.B.A., Analytical Program Steward, Teva Pharmaceuticals
12:25-1:25 p.m.	**Capsid Engineering and Screening Platform Developed New AAV for Different Organs** Daozhan Yu, Ph.D., CEO, AAVnerGene
Lunchtime Session: Finnegan Henderson	**Paoli Room**
Session host	Hui Wang, Ph.D., Head of US Business Development, Genevoyager
12:25-1:25 p.m.	**IP Considerations for Gene & Cell Therapy** Yieyie Yang, Ph.D., J.D., Partner, Finnegan Henderson
Lunchtime Session: uBriGene.	**Frazer Room**
Session host	Haichen Nie, Ph.D., Associate Director, Teva Pharmaceuticals
12:25-1:25 p.m.	**How Could CDMO and Technology Innovations make CGT Affordable?** Xiulian Sun, Ph.D., CTO, uBriGene

1:30-3:00 p.m. Parallel Sessions

Cell Therapy	**Centennial 1**
Session 2: Current Understanding and Management of Toxicities for Cell Therapy	
Session chair:	Jake Dong, Ph.D., Scientist, Cell Therapy, Johnson & Johnson Innovative Medicine
1:30-2:00 p.m.	**Hybrid CAR T Cells with Engineered Fuel Flexibility** Roderick O'Connor, Ph.D., Research Assistant Professor, Perelman School of Medicine, University of Pennsylvania
2:00-2:30 p.m.	**Nonclinical Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products** Gregory Conway, Ph.D., Pharmacology/Toxicology Reviewer, Office of Therapeutic Products, CBER, FDA

2:30-3:00 p.m.	**Mitigation Strategies to Address Potential Genomic Safety Risks of Allogenic Cell Therapy** Ilayaraja Muthuramu, Ph.D., Sr. Scientist, Johnson and Johnson

Clinical Development and Regulatory — Centennial 2

Session 2: Clinical & Regulatory Considerations for Cell Therapy in Hematology & Oncology

Session chair:	Yan Ni, Ph.D., Executive Director, Passage Bio
1:30-2:00 p.m.	**Catch Me if You Can: Resistance to CART Immunotherapy** Marco Ruella, M.D., Assistant Professor of Medicine, Division of Hematology and Oncology and Center for Cellular Immunotherapies, University of Pennsylvania
2:00-2:30 p.m.	**Comprehensive Clinical Pharmacology of Lisocabtagene Maraleucel for B-cell Malignancies** Ken Ogasawara, Ph.D., MPH, Director Clinical Pharmacology and Pharmacometrics, Bristol Myers Squibb
2:30-3:00 p.m.	**Clinical Pharmacology Considerations for CAR T Cell Therapy – a Regulatory Perspective** Xiaofei Wang, Ph.D., Sr. Clinical Pharmacology Reviewer, Office of Therapeutic Products, CBER, FDA

RNA and Gene Editing — Centennial 3

Session 2: Bioanalytical, DMPK and Clinical Pharmacology Strategies for In Vivo Characterization of Nucleic Acid Therapy

Session chair:	Peixin Zhu, Ph.D., VP, Editing Development, Verve Therapeutics
1:30-2:00 p.m.	**Characterizing ADME Properties of Lipid Nanoparticle (LNP) Encapsulated mRNA Therapeutic and Vaccine** Wenying Jian, Ph.D., Director, Bioanalytical Discovery and Development Sciences, Johnson & Johnson Innovative Medicine
2:00-2:30 p.m.	**A Bioanalytical Strategy for the Antisense Oligonucleotide** Xinqun Irene Wu, M.S., Sr. Scientist, Clinical Pharmacology, Pharmacometrics, Disposition & Bioanalysis, Bristol Myers Squibb
2:30-3:00 p.m.	**Predicting Clinical PK/PD and Impacts of Organ Impairment to Support Clinical Development of siRNA-based Therapeutics Using a**

Mechanistic Physiologically Based Pharmacokinetic and Pharmacodynamic (PBPK-PD) Platform Model
Annie Lumen, Ph.D., Scientific Associate Director, Clinical Pharmacology Modeling and Simulation, Amgen

Business	**Frazer Room**

Session 2: From the Bench to the Board Room: Navigating the World of Entrepreneurship, Innovation and Corporate Venture Capital in the Biotech Industry

Session chair:	Bill Lu, M.B.A., Principal Consultant, Forerun Advantage
1:30-2:30 p.m.	**Speaker:** Marian Nakada, Ph.D., VP of Venture Investments J&J Innovation-JJDC
3:00-3:15 p.m.	**Coffee Break and Networking**

3:15-4:45 p.m. Parallel Sessions

Clinical Development and Regulatory	**Centennial 2**

Session 3: TBD

Session chair:	Tao Niu, Ph.D., Director, Quantitative Clinical Pharmacology, Sarepta Therapeutics
3:15-3:45 p.m.	**Considerations for Immunogenicity Assessment in AAV-based (in-vivo) Gene Therapy (GTx) Development** Emmanuel Adu-Gyamfi, Ph.D., Director, Global Regulatory Sciences (Gene and Cell Therapy), Bristol Myers Squibb
3:45-4:15 p.m.	**Title: TBD** Yingjie (Jason) Huang, M.D., CMO, XlifeSc Ltd.
4:15-4:45 p.m.	**Comparison of Assay Performance Between Quantitative qPCR and a Nanoplate Based dPCR for use in Biodistribution Studies** Yanchun Li, Ph.D., Sr. Scientist, Johnson & Johnson

Business	**Grand Ballroom**

Session 3: Talk-To-An-Investor

Session chair:	Austin Duke, Ph.D., Managing Director, BroadOak
2:40-4:45 p.m.	**Investor/advisors:** • Austin Duke, Ph.D., Managing Director, BroadOak • James Fendrick, B.S., President & CEO, Rockland Immunochemicals • Glenn Gaddy, Ph.D., Managing Member, Robin Hood Ventures • Paul Hoerbelt, Ph.D., Director, Biotechnologies, Research Corporation Technologies

- Gregory Jackson, EVP, Life Science Greenhouse Investments
- Rick Jones, M.D., M.B.A., Partner, BioAdvance
- Steve Manobianco, M.B.A., Managing Director, PSG Life Sciences
- Bryan Poltilove, M.B.A., Consultant, BroadOak Capital Partners
- Heather Steinman, Ph.D., M.B.A., SVP, Business Development & Executive Director, Technology Transfer at The Wistar Institute

World Cafe Chat - Networking, Q&A

4:45-4:50 p.m.	**Concluding Remarks and Raffle Draw**
4:50-5:45 p.m.	**Reception**

CONFERENCE ORGANISING COMMITTEE

Leadership Team

Program Director and Chair	Lu Wang
Conference Co-Chair	Yufeng Li, Yang Yuan
Program Co-Director	Tao Niu, Saisi Xue, Fang Shen

Advisory Co-Chair

Haichen Yang Jing Yang

Advisory Committee

David Chang Jim Fendrick Frederick (Rick) Jones

Operating Committee	**Name**
Marketing/Communication	Namila FNU, Patricia Tsao
Project Management	Jin Wen, Shuo Huang
IT/Website	Ruixi Wang, Dian He, Ronghui Zhou
Logistics	Sherry Wang, Yifan Gong
Business Development	Hui Wang
Public Relations	Bill Lu
Engagement and Outreach	Haichen Nie

Track Leads	**Name**
Gene Therapy	Chunjuan (CJ) Song, Yixuan Ming
Cell Therapy	Tao Niu, Vibha Jawa, Shuai Dong
CMC	Huize Yan, Jin Wen, Long Geng
Clinical & Regulatory	Tao Niu, Mitra Tavakkoli
RNA Therapy	Tao Niu
Business	Fang Shen, Bill Lu, Jing Yang, Lisa Berger Baskin
Company Showcase/Lunchtime Sessions	Hui Wang

Session Chairs and Hosts

Austin Duke	Bryan Tsao	Guangyu Dong	Jingwen Niu	Lili Wang	Marcia Zaruba O'Connor
Matt Cabrey	Michele Washko	Mitra Tavakkoli	Peixin Zhu	Sima Kulkarni	Steve Jannetta
Ying Zhou	Yu-Chih Hsu	Xinjun Zhang	Zhiyi Cui		

Volunteers

Alan Zhou	Allison Tang	Celina Zhang	Chao Li	Chunying Song	Derui Huang
Elyssa Yang	Fei Meng	Hailey Deng	James Huang	Jialie Luo	Jingwen Niu
Jiong Wang	Kaixuan Liu	Keman Xu	Li Chen	Melinda He	Qiang Wang
Rufei Tang	Ruyu Shi	Sarah Weng	Sarah Xue	Serena Dong	Selina Chen
Shihao Fang	Si Ouyang	Sophie Johnson	Tianying Jiang	Tracy Chen	Vivian Peng
Xiaomei Wang	Xiaoting Ma	Yan Ni	Yifang Wang	Youjie Xu	Zak Huang
Zoe Zhang					

KEYNOTE SPEAKERS DAY ONE

Peter Marks, Ph.D., M.D.
Director
Center for Biologics Evaluation and Research, FDA

Peter Marks received his graduate degree in cell and molecular biology and his medical degree at New York University and completed Internal Medicine residency and Hematology/Medical Oncology training at Brigham and Women's Hospital in Boston. He has worked in academic settings teaching and caring for patients and in industry on drug development and is an author or co-author of over 100 publications. He joined the FDA in 2012 as Deputy Center Director for CBER and became Center Director in 2016. Over the past several years he has been integrally involved in the response to various public health emergencies, and in 2022 he was elected a member of the National Academy of Medicine.

Jason Bock, Ph.D.
CEO
CTMC

Jason Bock, PhD, is CEO of CTMC, a joint venture between Resilience + MD Anderson Cancer Center. Formed in May 2022 to accelerate patient access to impactful cell therapies by bridging cell therapy development and manufacturing with MD Anderson's clinical trial capabilities. In 2019, Jason was recruited by MD Anderson from Teva Pharmaceuticals to build the Biologics Development group. The group purchased a 60,000 SF facility in the Texas Medical Center and has since formed multiple partnerships with both MD Anderson faculty and early-stage biotech firms to bring their products through the IND process. Previously, Jason was Site Head and VP of Global CMC Biologics in the Specialty R&D Division of Teva Pharmaceuticals. He joined Teva through the acquisition of CoGenesys, a private biotech firm as a spinoff from Human Genome Sciences (HGS), where he worked after completing a PhD at Stanford University in Molecular & Cellular Physiology.

KEYNOTE SPEAKERS DAY TWO

Guangping Gao, Ph.D.
Professor & Director, Horae Gene Therapy Center
UMass Chan Medical School

Guangping Gao, PhD is the Director, Li Weibo Institute for Rare Diseases Research, Director, Horae Gene Therapy Center and Viral Vector Core, Professor of Microbiology and Physiological Systems, Penelope BoothRockwell Professor in Biomedical Research, UMass Chan Medical School; Elected fellows, both the US National Academy of Inventorsn(NAI) and American Academy of Microbiology; Past president, American Society of Gene and Cell Therapy.

Dr. Gao is an internationally recognized gene therapy researcher who has played a key role in the discovery and characterization of new family of adeno-associated virus (AAV) serotypes, which was instrumental in reviving the gene therapy field, hugely impacting many currently untreatable human diseases. For 30+ years of his scientific research career, Dr. Gao has primarily focused on molecular genetics and viral vector gene therapy of rare genetic diseases, encompassing disease gene cloning, causative mutation identification, pathomechanism investigation, animal modeling, novel viral vector discovery and engineering for in vivo gene delivery, vector biology, preclinical and clinical gene therapy product development, viral vector manufacturing for preclinical and clinical gene therapy applications as well as technology platforms development as novel approaches for human gene therapy. Dr. Gao has published 380 research papers, 6 book chapters, and 5 edited books. Dr. Gao holds 253 patents with 530 more patent applications pending. He serves as Executive Editor-In- Chief of Human Gene Therapy and Senior Editor of the Gene and Cell Therapy Book Series. He also serves on Editorial Boards of several major gene therapy and virology journals, NIIMBL Viral Vector Steering Committee and NIH Study Sections. Dr. Gao has been ranked as the World Top 20 Translational Researchers for several years in a row by Nature Biotechnology. Dr. Gao is a cofounder for several gene therapy companies.

Philip J. Brooks, Ph.D.
Deputy Director
Division of Rare Diseases Research Innovation, National Center for Advancing Translational Sciences, National Institutes of Health

Philip J. (P.J.) Brooks is the deputy director of NCATS' Division of Rare Diseases Research Innovation. He also is the working group co-coordinator for the NIH Common Fund program on Somatic Cell Genome Editing, one of the leaders of the Platform Vector Gene Therapy (PaVe-GT) pilot project and the co-chair of the Bespoke Gene Therapy Consortium(link is external). He also represents NCATS in the International Rare Diseases Research Consortium (IRDiRC). In May 2022, Brooks was selected as the recipient of the 2022 Sonia Skarlatos Public Service Award(link is external) by the American Society of Gene & Cell Therapy for consistently fostering and enhancing the field of gene and cell therapy. Brooks received his doctorate in neurobiology from The University of North Carolina at Chapel Hill. After completing a postdoctoral fellowship at The Rockefeller University, he became an investigator in the NIH intramural program, where he developed an internationally recognized research program focused on two distinct areas: the molecular basis of alcohol-related cancer, and rare neurologic diseases resulting from defective DNA repair, including xeroderma pigmentosum, Cockayne syndrome and Fanconi anemia.

SPEAKERS

Emmanuel Adu-Gyamfi, Ph.D.
Director, Global Regulatory Sciences (Gene and Cell Therapy)
Bristol Myers Squibb

Emmanuel Adu-Gyamfi is a trained virologist with a PhD in Molecular Virology and Biochemistry from the University of Notre Dame (Indiana). He conducted his post-doctoral research under the mentorship of Dr Robert Lamb, at the Howard Hughes Medical Institutes, Northwestern University. His academic research interest primarily focused on viral replication, assembly, and the application of recombinant or engineered viral vectors in Gene and Cell Therapy. Emmanuel's career path has spanned both industry and government service. He worked as a Senior Scientist in Cell and Gene therapy at Pfizer Inc, were he led the company's platform technology development for gene and cell therapy products. He later transitioned to work at the FDA as a regulatory chemistry, manufacturing, and controls (CMC) reviewer for gene and cell therapies at the Office of Therapeutic Product (OTP), Center for Biologics Evaluation and Research, CBER/FDA. As an expert CMC reviewer, Emmanuel was involved in the review and approval of several commercial gene and cell therapy products and helped shape regulatory guidance and policy. He also championed and chaired multiple intra and inter Agency Working Groups while at the FDA. At present, he serves as the Director of Global Regulatory Sciences for Gene and Cell Therapy at Bristol Myers Squib (BMS) company, where he oversees various aspects of regulatory CMC activities including global submissions, guidance and policy.

Samir Afif, Ph.D.
Senior Account Manager, Life Science
QIAGEN

Dr. Samir Afif earned his PhD in Molecular Biology from the University of Southern California in 2018. Transitioning from academia, he has devoted himself to connecting scientists with the tools necessary for making the groundbreaking and crucial discoveries needed to advance public health and scientific knowledge.

Louis W. Beardell Jr., J.D., M.S.
Partner
Morgan, Lewis & Bockius LLP

Louis W. Beardell Jr. focuses his practice on intellectual property (IP) matters in connection with patent strategies, IP due diligence, litigation, and transactions. He assists clients in developing and implementing programs that protect products and inventions including trade secrets, particularly in the life sciences, technology, and financial services fields. For US and international clients, Louis negotiates and prepares the IP aspects of licensing and purchase agreements, as well as agreements relating to product and service supply, collaboration, research, consulting, patent litigation settlement, and material transfer.

Louis counsels on all matters related to patent strategies, patent validity, patent due diligence, and freedom-to-operate opinions. His clients include an array of US and international companies in pharmaceuticals, chemicals, biotechnology, agricultural science, medical devices, and food science as well as major venture capital funds.

As companies evolve and modernize the way they operate, Louis ensures that they are able to establish exclusive positions to protect how they do business through procuring business method patents, as well as evaluating patent validity and freedom-to-operate positions for computer and business method inventions. His ability to prosecute patents and handle important trade secrets allows him to counsel clients through the creation of a diverse assortment of IP programs.

Louis frequently lectures to academic institutions and professional organizations on a variety of IP topics. He has been hosted by US and international IP and business associations, as well as top law schools and business school IP and entrepreneur classes.

Melina Blees, Ph.D.
Site Head
BioLabs Philadelphia

Melina has a BA from Carleton College in Minnesota and an MS and PhD in Physics from Cornell University, where her

dissertation focused on using paper arts techniques to build nanoscale moving parts. She went on to a program-building postdoc at the University of Chicago, then worked as Director of Innovation for a startup consulting company. She was thrilled to come home to science as part of the international BioLabs network in 2018. Alongside the expert BioLabs Philly team, Melina launched the original Philadelphia site, the BioLabs graduate suites, external services projects, and the BioLabs incubator at the Curtis in Center City Philadelphia. She has had the privilege of working closely with many of the best biotech companies in the city, and is passionate about helping them move swiftly towards the clinic and stay connected to their peers and ecosystem resources. She is proud to have been recently voted Ecosystem Builder of the Year in the BioBuzz Annual Awards.

Kimberly Bunting, M.B.A.

Director, Human Capital Practice
The O'Connor Group

Kim comes with an over 20 year career in Human Resources. Her passion lies in fostering a culture of excellence, collaboration, and inclusion, and aligning HR strategy with business objectives and values. She is especially adept at navigating and leading change management initiatives.

With comprehensive expertise in benefits and compensation, recruitment, HR management, HRIS oversight, and organizational development, she brings a wealth of knowledge and experience to the table. She has led people and culture initiatives across diverse sectors, including technology, higher education, financial services and retail and in not for profit and for-profit organizations. Her specialties include talent acquisition, process improvement, project management, dashboard development, employee engagement, succession planning, and leadership development. She has built HR functions from scratch for organizations experiencing unprecedented growth and she has a keen focus on talent management and inclusion and diversity.

Kim joined the consulting ranks in 2021 and has been with The O'Connor Group since 2023. She heads up the Human Capital team and serves as a fractional CHRO and executive coach to her clients. Kim, a former Division 1 athlete and coach, lives in South Jersey with her husband Jake, her twins Emma and Lily who attend University of Southern California and play lacrosse, and her son William, who will be a junior at Lenape High School in Mount Laurel, NJ.

Laurie Burlingame, J.D., M.B.A.

Partner
Morgan, Lewis & Bockius LLP

Laurie A. Burlingame has a diverse practice representing clients on a broad spectrum of transactions in the life sciences and technology industries, including initial and follow-on public offerings, venture capital financings, de-SPAC transactions, and mergers and acquisitions (M&A). She regularly serves as outside general counsel to clients, advising management teams and boards of directors on a variety of matters throughout the lifecycles of various companies, including formation and founder issues, licensing transactions, strategic collaborations, commercial transactions, corporate governance, disclosure requirements, and other general corporate matters.

Laurie's clients include pharmaceutical, medical device, diagnostics, biological materials and tools, and technology companies. She also represents life sciences–focused venture capital firms in connection with their portfolio company investments.

Laurie is active in several nonprofit organizations, serving on the boards of directors for the Massachusetts chapter of the Association for Women in Science, Sitters Without Scholars, and Families for Depression Awareness. In addition, she is a mentor and speaker for various university and incubator programs and maintains membership in local technology and medical associations.

Jason N. Butler, Ph.D.

Managing Director
Citizens JMP

Jason Butler is a Managing Director and equity research analyst focusing on the biotechnology and biopharmaceutical industries. Additionally, Jason serves as Director of Healthcare Research, overseeing JMP's research coverage of the broader life sciences industry. Jason has followed the biotechnology sector as an equity analyst for nearly 15 years. Prior to joining JMP Securities, he served as a senior associate equity analyst at Rodman & Renshaw covering biotechnology companies focused on therapies for metabolic and infectious diseases. Jason won recognition in the 2020 Refinitiv StarMine Analyst Awards, ranking first in earnings estimation

in the Pharmaceuticals category. Jason holds a PhD in neuroscience and a Bachelor's degree in biology from Imperial College London.

Gregory Conway, Ph.D.
Pharmacology/Toxicology Reviewer
FDA

Dr. Gregory Conway is a Pharmacology/Toxicology Reviewer in the Office of Pharmacology and Toxicology (OPT), Office of Therapeutic Products (OTP) in FDA's Center for Biologic Evaluation and Research (CBER). Prior to joining the FDA in 2022, Dr. Conway worked as a Scientist in the Manufacturing Science and Technology Department at American Type Culture Collection (ATCC). Dr. Conway completed post-doctoral training at Fox Chase Cancer Center in Philadelphia where he was a NIH T32 trainee in Cancer Biology. Dr. Conway received a BA in Biochemistry and Molecular Biology from Boston University, a MA in Pharmacology and Toxicology from SUNY Buffalo, and a PhD in Molecular Medicine from the University of Maryland, Baltimore. He has prior research experience in ovarian cancer, homologous recombination, protease biology, and stem cell biology.

Kirsten Copren, Ph.D.
Director, Analytical Development
National Resilience, Inc.

As a seasoned leader in translational genetics and applied genome science, I've held pivotal roles throughout my career. Currently, I contribute to the advancement of the biomanufacturing industry at National Resilience, where I lead molecular analytical development for novel characterization and release assays focused on cell and gene therapy (CGT) products. Leveraging multiomic single-cell sequencing technologies, I drive innovation in this field. My passion is increasing access to lifesaving living medicines to patients with a high unmet need. I have specialized in rare genetic diseases including metastatic cancer, hematological malignancies, and autoimmune disorders.

Before my current position, I served as the Director of Nucleic Acid Technologies at the University of Pennsylvania's Gene Therapy Program. There, I developed cutting-edge sequencing assays for pre-clinical in vivo AAV studies, including single cell transcriptomics, off-target detection, and long read sequencing. My journey to Penn followed the successful launch of my first commercial product—a diagnostic test for the microbiome in the veterinary market for the start-up AnimalBiome. My product enabled a $10M successful seed round.

My post-graduate career began in laboratory medicine as the Technical Director of the Genome Analysis Core at the University of California San Francisco's Comprehensive Cancer Center. In that role, I played a crucial part in advancing cancer diagnostics and biomarkers through innovative approaches and fruitful industry partnerships.

The tidal wave of sequencing technologies is coming to biomanufacturing analytics. National Resilience has chosen to lead the change. We are developing novel quality control assays using bulk and single cell sequencing to replace compendial assays. Combining multiple tests in a single assay will decrease vein-to-vein time, cost, and labor while also providing clinically relevant product characterization data. Come learn if our leading innovations in quality control and technology development might benefit your gene modified cell therapy product development from early phase to clinical trials.

Hugh M. Davis, Ph.D.
CB & DO, President
Biosion, Inc.

Dr. Davis is currently the Chief Business & Development Officer of Biosion, Inc. and President of Biosion USA, Inc. In these roles, Hugh has been instrumental in creating multiple partnerships for key therapeutic assets with US-based public companies and has built the development organization for Biosion including Preclinical and Translational Sciences, Clinical, Regulatory and Quality functions. Through this effort Biosion has advanced programs in Immunology and Oncology into the clinic, including phase 2 development of an anti-TSLP mAb for moderate to severe atopic dermatitis and asthma.

Dr. Davis has a 35+ year career in the discovery and development of novel therapeutics at major pharmaceutical and biotechnology companies, including 20 years at Johnson & Johnson. Hugh is an expert in the early development of innovative biologics, from asset discovery and characterization through IND and BLA regulatory submissions across the world, including the US, China, EU and Japan. Together with his team, Dr. Davis was instrumental in the development and approval of many biologic therapies at J&J including Remicade, Stelara, Simponi, Sylvant, Darzalex and Tremfya.

Hugh was the Vice President and Head of the Biolog-

ics Development Sciences department in Janssen Biotherapeutics (JBIO), leading a group of up to 200+ scientists in the biophysical characterization of discovery assets, translational methods to characterize leads, employ modeling and simulation to determine starting doses for first-in-human trials and develop novel clinical trial designs to achieve early clinical POC assessment of novel therapeutics. In addition, while in JBIO at Johnson & Johnson, Hugh was also the China Biologics Leader.

Dr. Davis holds a Ph.D. degree in Biochemistry from Villanova University and completed post-doctoral training at Centocor, Inc. where he patented the characterization of the tumor biomarker for ovarian cancer, CA125.

Patrick M. Denninger, B.S.
CEO
CellPort Software

Patrick M. Dentinger is a leading entrepreneur and executive in the life sciences and biotechnology sectors. Since January 2022, he has served as the Founder and CEO of CellPort Software, LLC, focusing on cloud-based cell processing platforms for life-science applications. Previously, Patrick co-founded Absorption Systems LP in 1996, with co-founder Dr. Ismael Hidalgo, and served as President and CEO until November 2020. Absorption pioneered the first validated, cell-based assay for bioequivalence testing, enabling generic drug approvals without human trials. This innovation established Absorption Systems as a global leader in Biowaiver testing. Absorption also developed the first cell-based potency assay for allogeneic gene therapy release testing in the U.S. and created cell-based, IND-enabling drug transporter models. Patrick's visionary leadership and strategic expertise have driven significant advancements in cell-based technologies. He holds a B.S. in Pharmacology from the University of California, Santa Barbara, underpinning his successful career in biotechnology.

Jing Fan, Ph.D.
Founder & CEO
Hopstem Biotechnology

Dr. Jing Fan received her bachelor 's degree at Peking University, Ph.D in Neuroscience at UBC, and postdoctoral training at Johns Hopkins University. She has been elected as one of the '30 Global Innovative talents of Chinese entrepreneurs' in 2018, the 2022 Forbes list "TOP50 Women in Science and Technology in China", the "Outstanding founder in biotechnology industry of 2022" BioCon Award, etc. Dr. Jing Fan has more than 20 years of experience in the fields of pluripotent stem cell and neural differentiation, CNS diseases and drug discovery. She has published more than 10 academic papers and book chapters on top journals and led the Maryland Stem Cell Foundation project, and participated in major R&D projects such as NIH, Helis Foundation, etc. Since 2017, she has founded Hopstem, led the team to establish advanced CMC and development platform for iPSC-derived neural cell therapy products and raised more than 70 million USD. The global first-in-class human forebrain neural progenitor cell injection hNPC01 received IND clearance from FDA in 2024 and is undergoing a registered phase I clinical trial targeting chronic ischemic stroke in China.

Glen Gaddy, Ph.D.
Managing Member
Robin Hood Ventures

Glen Gaddy has experience in technology, life sciences, advanced materials, real estate, consumer product development and venture funding. He has been an active angel investor since 2003, funding technology, life sciences, real estate, day care and business services ventures. His prior experience includes heading a research and development laboratory for a leading building materials company, leading real estate services for the world's largest consulting engineering firm and running a closely held real estate investment company. He has published in professional journals and has served as the Principal Investigator on over $8M of government research programs. He is an active reviewer of applied research grant applications in both the United States and abroad, an active speaker on startups and early-stage funding, and the reviewer of numerous business plans each year. He holds a Ph.D., M.S.E and B.S. in Materials Science and Engineering from the Johns Hopkins University.

Amy Gallagher, B.S.
Principal Scientist, Analytical & Quality Control
Spark Therapeutics

Amy Gallagher received her BS in Biochemistry and Molecular Biology from UC Santa Cruz and has more than 17 years of analytical experience across multiple modalities including vaccines, proteins, and nucleic acids. Amy joined Spark Therapeutics in 2021 and is currently a Principal Scientist in the Analytical Program Development & Management group where she supports multiple rAAV gene therapy programs. In this role she works closely with the CMC teams and analytical subject matter experts to develop and drive analytical strategy across the portfolio.

Maurits Geerlings, M.D.
President & CEO
Nanocell Therapeutics, Inc.

Dr. Geerlings is an experienced executive and serial entrepreneur who has co-founded and led multiple successful biotech companies . In 2000, he co-founded Actinium Pharmaceuticals Inc., a company listed on the New York Stock Exchange (NYSE: ATNM). In 2010, he established Formula Pharmaceuticals Inc., which was subsequently sold in 2020. In 2017, he co-founded Mirata Pharmaceuticals and launched NanoCell Therapeutics in 2021, both companies securing venture capital funding.

Dr. Geerlings played a key role as the Executive Vice President and Chief Operating Officer in Actinium Pharmaceuticals Inc., From 2002 to 2010, he has been actively involved in business development for Alexion Pharmaceuticals Inc., Cephalon, Inc., Prism Pharmaceuticals, and Infinity Pharmaceuticals.

Throughout his career, he has successfully navigated complex negotiations and spearheaded strategic partnerships. With extensive expertise in deal making, Dr. Geerlings has established alliances through out-licensing, in-licensing, M&A, plus co-development initiatives, spanning both domestic and international markets, including the USA and Europe.

Rebecca L. Grant, DVM
Director, Life Sciences & Biotechnology
City of Philadelphia

Rebecca L Grant, DVM, Director, Life Sciences and Biotechnology Rebecca attended Tuskegee University where she obtained her undergraduate and doctorate degrees. After graduating she practiced clinical veterinary medicine in Knoxville, Tennessee. Looking for a change in her career path, Rebecca came to Pennsylvania to complete a post-doctoral fellowship in Laboratory Animal Medicine at the R.W. Johnson Pharmaceutical Research Institute (Johnson & Johnson). After her fellowship she accepted a position in Dr Jim Wilson's Gene Therapy Program, as Director of the Nonhuman Primate Research Program. After almost 14 years at Upenn Rebecca decided to fulfill her desire to teach lower school for a few years. Missing the world of research, she accepted a position managing a bioengineering laboratory for Dr Susan Margulies at Emory University and GATech. In GA Rebecca established the laboratories for Dr Margulies and helped develop and perform studies looking at mild traumatic brain injury in youth. Wanting to return to Philadelphia, Rebecca moved back where she managed programs for Charles River Laboratories, then Cambridge Innovation Centers (CIC) before accepting a position as Director of Life Sciences and Biotechnology with the City of Philadelphia.

Jenny A. Greig, Ph.D.
Executive Director, Gene Therapy Program
University of Pennsylvania

Jenny Greig has a Bachelor of Science (Hons) in Pharmacology and a Ph.D. in Gene Therapeutics from the University of Glasgow in Scotland. Jenny joined the University of Pennsylvania's Gene Therapy Program (GTP) in 2010 as a post-doctoral researcher investigating muscle and liver transduction with gene therapy vectors. In her current role at GTP, she leads multiple therapeutic area groups focused on gene editing, oncology, and capsid engineering.

Rebecca Guzman, J.D.
Partner & Vice Chair, M&A Division
Duane Morris LLP

Rebecca Guzman is a corporate transactional partner at the law firm of Duane Morris LLP. She focuses on the representation of start-up and emerging growth companies with a focus on life science. Her practice spans the entire corporate lifecycle, from formation through liquidity. In addition to her company client counsel, Rebecca represents a number of prominent venture capital funds and institutional investors in their financing activities. Rebecca is broadly experienced in M&A and currently serves as a vice chair of the M&A Division of the firm. She also has extensive experience and regularly advises in all areas of Delaware corporate and alternative entity law. Rebecca was named to Best of the Bar by the Philadelphia Business Journal, a Most Effective Deal Maker by the Legal Intelligencer and named to the Delaware Business Times' 40 under 40, an annual list that recognizes the best young professionals under the age of 40 in the State of Delaware. Rebecca is a graduate of the University of California, Berkeley, School of Law, where she won the Prosser Prize in Negotiations, and a graduate, with highest honors, of Lehigh University, where she was elected to Phi Beta Kappa. Before law school, Rebecca was a Fulbright Scholar in Jakarta, Indonesia

Andrew Haupt, J.D.
Partner
Morgan, Lewis & Bockius LLP

Andrew Haupt represents emerging to multinational life sciences companies in all aspects of their legal affairs, including complex license, collaboration and other partnering agreements, mergers and acquisitions, venture capital financings, and other financial and commercial transactions. His clients include pharmaceutical, biotech, vaccine, medical device, technology, and emerging growth companies as well as private equity firms. Prior to private practice, Andrew was corporate counsel to a publicly traded biopharmaceutical company.

Chunyan He, Ph.D.
CEO
Suzhou GenAssist Therapeutics Co., Ltd

Dr. Chunyan He has received her Ph.D degree in Immunology in Shanghai Jiao Tong university. She had worked in different departments of pharmaceutical industries, including RD, QC, Manufacturing, BD and M&A. In June 2020, Dr. He founded Suzhou GenAssist Therapeutic Co., Ltd, the leading biotech company focusing in DMD treatment in China.

Paul Hoerbelt, Ph.D.
Director, Biotechnologies
Research Corporation Technologies

Paul investigates new investment and business growth opportunities in life science tools, services, and therapeutics. Before joining RCT, he was at L.E.K. and then at Illumina Ventures.

Yingjie J. Huang, M.D.
CMO
XlifeSc Ltd

Yingjie (Jason) Huang, MD. serves as the Chief Medical Officer in XlifeSc Ltd, a company specializing in cell therapy for solid tumors. Prior to joining XlifeSc, he held key position at various China-based biotech and pharma companies: served as the CMO (oversea) at Fusun Pharma, and held the postion of senior vice president of clinical development at Acentage and Transcenta. Additionally, Dr. Huang has worked in several global pharmaceutical companies including Novartis, Bristol-Myers-Squibb and GlaxoSmithKline, where he served as a global or Asia-Pacific regional clinical leader for prominent oncology projects. Throughout his career, Dr. Huang has led comprehensive clinical development initiatives, overseeing projects from Phase 1 through Phase 3/4 trials. His responsibilities have included strategic planning, study execution, and regulatory submissions. Dr. Huang began his career as an on-

cologist at the Cancer Center of Sun Yat-sen University and later pursued postgraduate training in clinical epidemiology at Queen's University at Kingston. Dr. Huang received his medical degree from Sun Yat-sen University of Medical Sciences.

Tonya Hutchison, M.B.A., B.S.

Sr. Director, Quality Control Operations
Spark Therapeutics

Tonya Hutchison has been with Spark for two years. She is responsible for all aspects of GMP Quality Control Operations for clinical & commercial programs across Spark. This includes oversight of raw materials, environmental monitoring, microbiology, release testing of drug product, drug substance & in-process samples and ownership of the critical reagents, stability, sample management, contract testing laboratory, and data review programs. Prior to Spark, Tonya spent nearly 13 years with Merck & Co leading in several different areas including QC Laboratory Operations Vaccines, Supplier Management, & as a Site Quality Head Small Molecule Pharmaceutical Operations. Tonya earned her Bachelor's Degree in Biochemistry & Molecular Biology from Pennsylvania State University, holds a Masters in Business Administration from DeSales University, and is a certified Lean / Six Sigma Black Belt. Tonya is married to her husband, Ryan, has three beautiful nieces, and two dogs.

Greg Jackson, Ph.D.

EVP
Life Sciences Greenhouse Investments

Gregory R. Jackson, Ph.D., is Executive Vice President of Life Science investments. Among his responsibilities are identification of new investment opportunities and conducting due diligence, as well as mentoring and monitoring performance of portfolio companies.

Greg was Co-Founder and Chief Technology Officer of MacuLogix, Inc., an ophthalmic medical device company, and has a total of 19 years' experience in the medical device industry. Prior to co-founding MacuLogix, Greg spent 15 years in academic medical research, most recently as an Associate Professor of Ophthalmology at Penn State College of Medicine from 2007 to 2014. Greg began his academic career as an Assistant Professor of Ophthalmology at the University of Alabama at Birmingham.

Dr. Jackson holds a Bachelor of Science degree from Clarion University of Pennsylvania, and a Ph.D. from the University of Alabama at Birmingham.

Stephen A. Jannetta, J.D.

Partner
Morgan, Lewis & Bockius LLP

An active member of the local legal and business communities, Stephen A. Jannetta provides for-profit and nonprofit clients in the life sciences, healthcare and healthcare insurance, and health information technology with corporate advice and counsel. His clients include public and privately held corporations and nonprofit corporations and Steve regularly advises them on complex matters, including equity and debt financing transactions, mergers and acquisitions, joint ventures and corporate governance issues.

Steve has been an active member of the board of directors for Life Sciences Pennsylvania, the state's trade association for the life sciences industry, and he twice chaired the association's annual life sciences conference. He is the honorary consul of the Kingdom of Belgium for the Philadelphia region. Steve also serves as counsel to The Chamber of Commerce of Greater Philadelphia, the Philadelphia region's nonprofit charged with promoting growth and business opportunities in the Philadelphia region.

Serving on various other boards, Steve has been a member of the board of trustees of his alma mater, The Episcopal Academy, a private, coeducational school; and a member of the campaign cabinet of the United Way of Greater Philadelphia & Southern New Jersey. He also is a member of the advisory board for the Hubert J.P. Schoemaker Classic, an annual event benefiting Melmark Inc., a nonprofit organization that provides educational services to children and adults with intellectual challenges, and a member of the President's Advisory Council for Christo Rey Philadelphia High School, a private Catholic college preparatory school for children of all faiths.

Wenying Jian, Ph.D.

Director
Johnson & Johnson Innovative Medicine

Dr. Wenying Jian is currently a Director of Bioanalytical Discovery and Development Sciences (BDDS) of Johnson & Johnson Innovative Medicine. She is leading a team to support discovery bioanalysis across modalities including small molecules, biologics, ADCs, and oligonucleotides. She also serves as function representative for novel modalities such as LNP encapsulated mRNA. Wenying has over 19 years of industrial experience with Bristol-Myers Squibb and then Johnson & Johnson. She has published over 60 journal papers and book chapters, and co-edited the book "Targeted biomarker quantitation by LC-MS" and "Sample preparation in LC-MS bioanalysis". She currently serves on the editorial board of Journal of Pharmacological and Toxicological Methods. Wenying received her B.S. in Pharmacy from Beijing Medical University, M.S. in Microbiology from Chinese Academy of Sciences, and Ph.D. in Pharmacology from University of Pennsylvania.

Kaiyuan Jiang, Ph.D.
Associate Director, Cell Therapy Process Development
Johnson & Johnson Innovative Medicine

Dr. Kaiyuan Jiang is an associate director of cell therapy process development at Janssen Research & Development in Pennsylvania, U.S. He is currently leading a team to develop next-generation cell manufacturing platforms for autologous and allogeneic cell therapy programs. Dr. Jiang was a senior engineer and team lead to support the research, process development, technology transfer and regulatory submission of several clinical CAR-T programs at Kite/Gilead Sciences. He graduated from the PhD program of Biomedical Engineering at University of Florida. His experience was focused on developing immunomodulating strategies for cell transplantation treating Type 1 diabetes, as well as end-to-end drug product development of autologous and allogeneic CAR-T cell therapies. As a leading author, Dr. Jiang has published several research articles on high-impact journals and patent applications in the field of biomedical engineering.

Sunil Joshi, M.B.A., M.S.
President
Strategius Consultants

Prof. Sunil Joshi, MSc MBA, is senior BioPharma executive and board member with a distinguished career spanning three decades across notable companies like BMS, Bayer, Onyx, Halozyme, and Gradalis Inc. His expertise in pharmaceutical medicine commercialization, coupled with his strategic prowess in clinical and commercial strategy and mergers and acquisitions, positions him as a leading thought leader in the field. Prof. Joshi's adeptness in investor outreach and capital raising underscores his ability to lead enterprises from the inception of Phase 1 clinical trials to the successful post-launch phase, marking him as a pivotal figure in the industry.

Throughout his career, Prof. Joshi has demonstrated exceptional leadership qualities as a biotech CEO and Pharma senior leader, boasting over a decade of governance experience. His knack for problem-solving, building high-performance teams, and mentoring senior leaders has contributed significantly to his success. As the former head of Strategy & Cell Therapy Unit for Oncology at Bayer Pharmaceuticals, Prof. Joshi has shown a broad range of experience, from leading drug development organizations for Phase I-III assets to spearheading sales and marketing for today's cutting-edge precision medicines.

Currently, as the President of Strategius, a strategy consulting firm, Prof. Joshi continues to influence the Pharma and Biotech industry. His role as an educator at Rutgers University allows him to share his vast knowledge and experience with the next generation of industry professionals. His contributions extend beyond his professional achievements, as he actively participates in business development, in-licensing, and the acquisition of innovative therapies, further highlighting his commitment to advancing healthcare solutions.

David J. Kellman, BSE
Managing Director & Head, Healthcare Investment Banking
Citizens JMP

David Kellman is a Managing Director and Head of Healthcare Investment Banking at Citizens JMP. Citizens JMP has a leading life sciences franchise, working with private and public companies on strategic transactions as well as accessing the equity and debt capital needed to advance development programs and support commercial launch. He has nearly 25 years of experience advising or investing in life sciences and biotech companies.

Prior to joining JMP, David was a Vice President at Paramount BioSciences, a life sciences investment firm. Previously, he was a hedge fund analyst at S.A.C. Capital Advisors focused on healthcare investing and a member of the healthcare investment banking group at Piper Jaffray. David began

his career in the healthcare group of Investor Growth Capital, the venture capital arm of Investor AB.

David holds a BS in finance from the University of Pennsylvania's Wharton School and a BSE in bioengineering from its School of Engineering and Applied Science.

Genevieve Laforet, Ph.D., M.D.
SVP, Clinical Development
Aspa Therapeutics/BridgeBio Gene Therapy

Genevieve (Jenny) Laforet, MD, PhD is Senior Vice President, Clinical Development at Aspa Therapeutics/BridgeBio Gene Therapy. She is the medical lead for Aspa's BBP-812 gene therapy program for Canavan disease. Before joining Aspa she served as Vice President of Clinical Research and Development at Solid Biosciences and led Solid's SGT-001 microdystrophin gene therapy program for Duchenne muscular dystrophy. Dr Laforet received her AB in Biochemical Sciences from Harvard College, MD from Duke University School of Medicine and PhD from The Rockefeller University. She trained as an adult psychiatrist at UMass Medical School and went on to conduct basic and translational research on Huntington's disease and Rett syndrome as a faculty member. Dr Laforet subsequently moved to the biotech/pharma industry and has worked in a variety of scientific/medical affairs and clinical development roles at Abbott, Biogen, Genzyme and Sarepta.

Yanchun Li, Ph.D.
Sr. Scientist
Johnson&Johnson

Dr. Yanchun Li is a senior scientist of Bioanalytical Discovery & Development Sciences department at Johnson & Johnson Innovative Medicine. She has intensive experience in Neuroscience and AAV-based Gene therapy. Yanchun now is leading method development/validation and bioanalysis for Genomic Therapeutics which includes Gene Therapy, Cell therapy, and RNA therapeutic vaccine projects.

Alvin Luk, Ph.D., M.B.A., CCRA
Co-Founder & CEO
HuidaGene Therapeutics

Dr. Alvin Luk is the co-founder and CEO of HuidaGene Therapeutics, a global clinical-stage biotech company developing CRISPR-based gene-editing tools and genomic medicines. Alvin has over 30 years of global drug development experience in biotech/biopharma organizations, including Shanghai-Henlius/Fosun-Pharma, Spark Therapeutics (acquired by Roche), Biogen (Hemophilia Business Unit acquired by Sanofi), Bayer, Avigen (acquired by Sanofi Genzyme), and Tularik (acquired by Amgen) with progressive responsibilities. While serving as the Chief Medical Officer at Shanghai-Henlius, a commercial-stage biopharma company focusing on biologics for oncological, autoimmune, and ophthalmic diseases, he led the approvals of 5 biological medicines in China, Europe, and the USA. Alvin was also the Head of Clinical and led multiple AAV gene therapy programs at Spark, where LUXTURNA. He has a proven track record of participating in more than 250 cumulative regulatory submissions across the globe, leading to the successful commercial launches of 21 approved products. He is the co-author of over 100 book chapters and scientific papers in highly regarded journals, including the New England Journal of Medicine, Nature Medicine, Cell, and Science. Dr. Luk holds an MBA from Harvard, received his Ph.D. in Neuroscience, and is certified in clinical research from the UCSF Medical School.

Annie Lumen, Ph.D.
Scientific Associate Director
Amgen

Dr. Annie Lumen is a Scientific Associate Director in the Clinical Pharmacology, Modeling and Simulation Department at Amgen. She comes from both biology and engineering background with more than a decade of experience in developing de novo mechanistic & PBPK models for various therapeutic modalities to support drug development, in her current position at Amgen, and for regulatory evaluations in her previous appointment as a Principal Investigator and Research Group Lead at the FDA.

Patrick Lundgren, Ph.D.
Investor
Hummingbird Ventures

Patrick focuses on biotech investments at Hummingbird and leads incubations. He's a big fan of "thoughtfully crazy" people building in bio. He was previously an Associate at Flagship Pioneering where he worked in venture creation to build and originate bioplatform companies. Before Flagship, Patrick completed his Ph.D. in immunology at the University of Pennsylvania, publishing 10+ papers including in Cell, Nature, and Nature Metabolism spanning adipocyte biology, immunology, and gut-brain signaling. Patrick also holds an M.Sc. in immunology from the University of Oxford (with Distinction), and a BA in Natural Sciences from the University of Cambridge. A native Swede, Patrick grew up in Malmö, which prepared him well for Boston winters.

Stephen Manobianco, M.B.A.
Managing Director
PSG Life Sciences, The Leader in Fractional Life Sciences Commercialization Services

Steve has over 25 years of global sales, marketing and business development experience. For a significant part of his professional career he has been working in the biopharmaceutical R&D service industry. Steve has a broad knowledge and expertise in the global research and development marketplace. He has a successful track record of creating and executing go-to-market business development strategies to effectively drive double digit revenue growth. Most recently Steve has been the Managing Director for PSG Life Sciences a leading biotech consulting firm. He has been working with the Rockland portfolio of companies for the past three years to create and drive strategic growth and revenue strategies and initiatives. Prior to PSG Life Sciences, he was the Vice President of Global Sales and Business Development for GENEWIZ. Steve holds a Bachelor's degree in Economics from Syracuse University and an MBA from Regis University, Denver Colorado.

Ian McLaughlin, Ph.D.
VP, Government Affairs
BioNJ

Ian McLaughlin, PhD, is the Vice President of Government Affairs at BioNJ, which is the trade association for the full spectrum of the life sciences ecosystem in New Jersey — from small biotech startups to the largest biopharma companies in the world — at both state and federal levels. Prior to joining BioNJ, Ian completed his PhD in neuroscience at the University of Pennsylvania where his research focused on identifying novel druggable targets to treat addiction and mood-related psychiatric conditions. His research combined chemogenetics, optogenetics, viral tracing, and behavioral pharmacology in animal models in pursuit of new opportunities to develop novel therapeutics. Between graduate school and BioNJ, Ian worked as a Policy Analyst in the New Jersey Legislature, focusing on health policy.

Ilayaraja Muthuramu, Ph.D.
Sr. Scientist
Johnson and Johnson

Dr. Muthuramu is a Senior Scientist at the specialized applied toxicology department of Johnson and Johnson Pharmaceuticals, where he partners with the therapeutic discovery genome editing group. In his current role he is actively involved in establishing external partnerships to perform off-target analysis and genomic stability testing, including translocation assessment, for the genetic toxicology safety assessments related to the allogeneic cell therapy platform. He is also leading the efforts to establish genomic safety assessment platform for the in-vivo gene editing therapies. Before joining Johnson & Johnson, he worked as a Principal Scientist at Frontage Laboratories and Ocugen. He was a subject matter expert and study director responsible for conducting GLP toxicology (study design, planning) and biodistribution studies for cell and gene therapy modifications. Dr. Muthuramu has obtained my Ph.D. in Biomedical Science from the Catholic University of Leuven, Belgium in 2015. Later, he joined Prof. Dr. Jim Wilson's lab at the University of Pennsylvania. He primarily worked on developing novel mouse models to evaluate in-vivo genome editing methods using CRISPR and ARCUS nucleases. He has authored or co-authored more than 20 peer

reviewed research articles in various high impact journals.

Marian Nakada, Ph.D.
VP, Venture Investments
Johnson & Johnson Innovation – JJDC

Marian Nakada, VP Venture Investments for Johnson & Johnson Innovation – JJDC, has over 30 years of experience in the pharmaceutical industry, starting her career at the laboratory bench at Centocor and moving to a research leadership role before Centocor's acquisition by Johnson & Johnson. She transitioned to Janssen Business Development and joined JJDC, Johnson & Johnson's corporate venture group in 2013. She is passionate about leveraging Johnson & Johnson's capabilities to help her portfolio companies succeed. Marian has a A.B. in Biology from Harvard College and a Ph.D. in Pharmacology from the University of Pennsylvania. She has authored 62 peer reviewed publications and 14 book chapters and is a past reviewer for the NIH Pharmacology Study Section. She is currently on the Boards of Redona Therapeutics, Navitor Pharmaceuticals, and a stealth NewCo as well as the New England Venture Capital Association where she is working to champion change as an active contributor to its diversity & inclusion efforts. Outside work, Marian is a Board Member at InnerCity Weightlifting whose mission is to amplify the voice and agency of people who have been most impacted by systemic racism and mass incarceration.

Michael F. Naso, Ph.D.
SVP, Research
Century Therapeutics

Michael Naso is a Senior Vice President in Research responsible for guiding the research of genetically engineered induced pluripotent stem cell (iPSC)-derived immune cell products to treat hematologic and solid tumors, as well as, autoimmune diseases. Prior to joining Century in January of 2019, he was a Director at Janssen Research and Development within the Biotherapeutics division, where he held leadership positions for programs and teams focused on antibody and cell and gene therapy discovery. Michael received his MS degree from Thomas Jefferson University in Anatomy, Cell Biology and Pathology, and his PhD from TJU in Biochemistry and Molecular Biology.

Ken Ogasawara, Ph.D., M.P.H.
Director
Bristol Myers Squibb

Ken Ogasawara, PhD, MPH is a Director of Clinical Pharmacology, Pharmacometrics & Bioanalysis - Hematology, Oncology & Cell Therapy (CPPB - HOCT) at Bristol Myers Squibb (BMS). Since he joined Celgene/BMS in 2018, he has been Clinical Pharmacology Lead of lisocabtagene maraleucel (liso-cel, Breyanzi) as well as several early/late development assets in HOCT. Prior to joining BMS, he received postdoctoral training at Medical College of Georgia, University of Rhode Island, and Division of Quantitative Methods and Modeling (DQMM), Office of Generic Drugs (OGD), CDER/FDA and worked as Clinical Pharmacokinetic Scientist in Eli Lilly Japan. He received his PhD in Pharmaceutical Sciences from Kyoto University, Japan, and MPH from Johns Hopkins Bloomberg School of Public Health. He has published over 50 peer-reviewed publications. He is serving as a member of several working group of Clinical Pharmacology Leadership Group (CPLG) in the IQ Consortium.

Noah Olson, M.B.A.
Director, Innovation
Delaware Prosperity Partnership

Noah Olson is the Director of Innovation at the Delaware Prosperity Partnership, a not-for-profit economic development organization charged with attracting businesses to Delaware, assisting with the growth of Delaware companies, and supporting and expanding the state's innovation and entrepreneurial ecosystems. With the massive growth of the life science sector in the region, particularly the Cell and Gene Therapy fields, it's an exciting, and busy time to be in economic development. Noah has a background in the public sector in Delaware, and joined DPP after completing business school at the University of Delaware. Noah's focus on innovation at DPP allows him to work with a variety of key stakeholders, in and outside of the state, to not only advocate for Delaware as a place to do business, but be on the forefront of organizing, convening, and pushing for additional programming to build out the innovation and startup or entrepreneurial ecosystem in Delaware. In 2022, Noah was named to the Delaware Business Times (DBT) 40 un-

der 40 list for achievers and innovators under the age of 40, and in 2023, Noah was a fellow in the prestigious Leadership Delaware program. Outside of the office, Noah is a dad, husband, a runner, and a proud two time University of Delaware Blue Hen.

Roddy O'Connor, Ph.D.
Research Assistant Professor
Perelman School of Medicine at the University of Pennsylvania

Dr. O'Connor's research emphasizes novel conditioning strategies and genetic approaches to confer unique metabolic attributes to CAR T cells. In collaborative research with Nucleus Biologics, Dr. O'Connor developed a customized, cGMP grade, CAR T cell culture medium for the University of Pennsylvania (UPenn) clinical sector. In a recent paper, he shared how this state-of-the-art medium formulation enhances CAR T cell potency and anti-tumor function. As medium composition can obscure metabolic responses induced by CAR co-stimulation, he recently designed a physiologic medium specifically for the Seahorse assay (Agilent Thought Leader Award). His team were also the first to show how nonnative enzymes increase the resilience of CAR T cells against metabolic (lactate, hypoxia) and immune (Siglec) checkpoints in solid tumor environments. His expertise in T-cell metabolism has been recognized through an Award for Excellence in Immunology (AAI) and exemplified by several industry sponsored research alliances with Seahorse Bioscience, Nucleus Biologics, and Agilent. At UPenn, his team is now poised to translate our advances in CAR T cell metabolic fitness to target various malignancies and auto-immune diseases. Dr. O'Connor is a highly regarded expert in CAR-T cell metabolism and has presented his findings at AAI, ASGCT, and the CAR-TCR Summit. Dr. O'Connor co-organizes the annual metabolomics symposium at UPenn and has presented several workshops as well as a webinar series with Nucleus Biologics on CAR-T cell metabolism.

Wendy Pan, Ph.D., J.D.
Partner
Goodwin Procter LLP

WENSENG "WENDY" PAN, JD & PhD, is a partner of Goodwin Procter, a leading internal law firm with top notch life sciences practices. She has advised biotech and pharmaceutical companies at all stages, addressing a broad spectrum of legal needs, from initial company formation, corporate governance, to growth stage financing, partnership and joint venture, to IPO. She has represented buyers, sellers, private equity and venture capital investors in mergers and acquisitions, stock and assets acquisitions/divestures, control acquisition, minority investments, going private, de-SPAC transactions. She has handled numerous strategic licensing and partnership deals between global pharmaceutical companies and biotech companies, involving small molecule, biologics, gene therapies, cell therapies, medical devices, diagnostic products. Apart from transactional practice, she also helps her clients in resolving contractual disputes in complicated life sciences partnership arrangements. Her deep legal experiences, coupled with her unparalleled understanding about the businesses and technologies and her pragmatic approach have won recognitions by IFLR1000 as a leading lawyer for M&A, Who's Who Legal: Life Sciences (Transactional). Wendy obtained her JD from Columbia University School of Law and a PhD in chemistry, also from Columbia. She is also a registered US patent attorney.

Sonali Patel, Pharm.D.
Director, Regulatory Affairs
Spark Therapeutics

Sonali Patel is a Director of Regulatory Affairs at Spark Therapeutics with oversight of global regulatory strategy across the CNS gene therapy portfolio as well as regulatory lead of several ongoing programs. Sonali is responsible for developing global regulatory strategies to support each program as well as leading health authority interactions with the cross functional teams. She joined Spark with over ten years of regulatory experience at Genentech across multiple therapeutic areas and therapeutic modalities in roles of increasing responsibility. Notably, Sonali served as a global regulatory leader for COVID-19 clinical programs during the height of the pandemic and was a US lead of a multiple sclerosis biologic licensing application from submission to approval. She received her Doctorate of Pharmacy (PharmD) from Rutgers, the State University of New Jersey, and her Post-Doctoral Fellowship in Regulatory Affairs from Roche/Genentech.

Vikram Patra, M.B.A.
Managing Director
Freedom Capital Markets

Vikram is a Managing Director at Freedom Capital Markets – a small and mid-cap focused investment bank in New York.

Vikram has over 18 years of experience across public and private capital markets and he focuses on advising clients in healthcare and technology sectors on strategic and financing matters. Over his career, Vikram has worked on over 140 transactions raising over $70 billion for clients.

Prior to joining Freedom, Vikram was one of the founding members of Nomura's investment banking business in the Americas and he was also an investment banker at UBS and Wells Fargo earlier in his career.

Vikram holds an MBA from the Darden Graduate School of Business at the University of Virginia and a Bachelors of Science in Electrical Engineering from the National Institute of Technology, India

Mrunalini Vikram Pattarkine, Ph.D.
Professor Biotechnology, heads the BTEC program
Harrisburg University of Science and Technology

Mrunalini Pattarkine, PhD, Professor Biotechnology, heads the BTEC program at Harrisburg University of Science and Technology in Harrisburg PA USA. Prof Pattarkine has a PhD in Biochemistry from IIT Powai, and has over 25 years of research experience. She is the lead faculty for MS BTEC as well as the Nanobiotechnology initiative within the Biotechnology program at the university and is currently directing sponsored research for private industries. In addition to teaching Biotechnology/Nanobiotechnology courses, Prof Pattarkine also serves as a Director of Capital Area Biotechnology Partnership (CABP), a Workforce Leadership Grant in Biotechnology initiated in 2007 though funding from PA Department of Community and Economic Development (DCED). Prof Pattarkine has active research projects in areas such as biosensor development, paper-based analytics, antimicrobial properties of plant biomaterials, 3D Bioprinting of Skin tissue, and hydrogels for regenerative medicine. Prof Pattarkine has several publications and several book chapters to her credit. She has conducted numerous workshops at national and international events, for educators and administrators.

Renuka Pillutla, Ph.D.
SVP & Head, Development Sciences
Spark Therapeutics

Renuka Pillutla is Senior Vice President and Head of Development Sciences, Technical Development and Analytical Development & QC at Spark Therapeutics, a subsidiary of Roche.

In her current role she plays a key leadership role at Spark by providing strategic and scientific leadership to the development of gene therapies. She is responsible to ensure preclinical and clinical strategies for biodistribution, PK/PD, safety, pharmacology, translational, biomarker, bioanalytical, companion diagnostics, technical and analytical development are established and implemented in an efficient and integrated fashion.

Her responsibilities in development of investigational gene therapy drug candidates span from early discovery through major milestones such as IND, FIH and all phases of clinical development through to regulatory filing.

Prior to Spark, Renuka spent 11 years at Bristol Myers Squibb in various leadership roles in translational medicine, bioanalytical sciences, nonclinical and clinical development.

During the course of her career Renuka has worked in drug discovery (Discovery Research), and various areas of Drug Development such as CMC analytical, bioanalytical, translational, preclinical & clinical. The diversity of her experience provides her with a well-rounded knowledge of all aspects of drug development.

Bryan Poltilove, M.B.A., B.S.
Consultant
BroadOak Capital Partners

As Operating Partner, Mr. Poltilove leads BroadOak's investment strategy in Cell and Gene Therapy, Bioproduction, and Cell Biology. Mr. Poltilove joined BroadOak after 12 years with Thermo Fisher Scientific where he served as Vice President and General Manager. Mr. Poltilove led long-range strategy and day-to-day operations for the company's cell and gene therapy business. Prior to Thermo Fisher, Mr. Poltilove served

as Director of Revenue Strategy & Operations at the Corporate Executive Board and also held several commercial strategy roles with Johnson & Johnson. He holds Bachelor's degrees in Chemical Engineering and Economics from the Massachusetts Institute of Technology as well as an MBA from the J.L. Kellogg School of Management at Northwestern University.

Meghan Popoleo, B.S.
Vice President of Growth
The O'Connor Group

Meghan Popoleo is the Vice President of Growth at The O'Connor Group, a leading HR Outsourcing and Recruitment firm based in King of Prussia, PA. In this role, Meghan drives strategic initiatives that foster business growth and enhance employee engagement and retention, with a particular focus on the life sciences sector, including cell and gene therapy companies.

With specialties in sales, marketing, and client engagement, Meghan leverages data-driven strategies to deliver measurable results for TOC's clients. She is passionate about the people function and its critical role in organizational success, creating programs that build positive work environments and collaborative cultures.

Before joining The O'Connor Group, Meghan gained valuable experience across diverse industries, including nonprofit, clinical research, and private equity. This varied background gives her a unique perspective and a well-rounded approach to employee attraction and retention.

Meghan holds a Bachelor of Science degree from James Madison University. She is actively involved in her community, serving on the Women's Resource Center (WRC) Board of Directors and a former board member of Philadelphia's chapter of Women in Bio (WIB).

Irene Rombel, Ph.D., M.B.A.
CEO, President & Co-Founder
BioCurie

Dr. Irene Rombel is the CEO, President and Co-Founder of BioCurie, a TechBio startup company that is harnessing AI to transform the process development and manufacturing of cell and gene therapies. She is deeply committed to transforming great science and technology into disruptive products that will help patients and society, while creating shareholder value. Dr. Rombel is an industry veteran and entrepreneur with 25+ years of leadership experience in science and business, spanning biotechnology, big pharma, consulting, investing, and academia. Prior to founding BioCurie, she was Chief of Staff, Research, at Spark Therapeutics, and Senior Director of Strategy and External Innovation at Janssen, J&J. Irene was previously the Founder and President of Biomedical Intelligence LLC, a life science consulting company, and a biotech hedge fund analyst. Dr. Rombel started her career in academia as an Assistant Professor at UT Southwestern Medical Center in the Center for Biomedical Inventions, where she conducted research on DNA vaccines, synthetic biology, and cell-specific targeting. Prior to her faculty position, she was a postdoctoral fellow at UC Berkeley and UC Davis, where her research on transcriptional regulation made fundamental scientific contributions to the understanding of promoter-enhancer control of gene expression. Dr. Rombel has advised and mentored many start-up companies over the past 20+ years, serving as a JPAL for the J&J JLABS Incubator companies, and as a Scientific Advisory Board member of the North Texas Enterprise Center. She is on Columbia University's Translational Therapeutics Accelerator Steering Committee and the Columbia University Irving Cancer Drug Discovery Advisory Board. Dr. Rombel received her Ph.D. in Biochemistry and B.Sc. (First Class Honors) in Biochemistry with a double major in Microbiology from the University of Otago, New Zealand, and her MBA from Southern Methodist University, Dallas, Texas. Irene is also a registered U.S. Patent Agent with the USPTO.

Heather Rose, Ph.D., J.D.
VP, Technology Licensing and Start-ups
Thomas Jefferson University & Jefferson Health

Heather Rose PhD, JD is the Vice President of Technology Licensing and Start-Ups for Thomas Jefferson University and Thomas Jefferson Health. In her role at Jefferson, Dr. Rose oversees a dynamic team that collaborates with researchers and physicians to lead projects to value inflection points, file patent applications for novel innovations, assist with start-up company formation, and manage existing relationships with corporate sponsors and licensees.

Over her career, Dr. Rose has collaborated with researchers, physicians, and attorneys to file over 700 patent applications and negotiated over 400 agreements, including 150+ licenses, sponsored research, option, and equity agreements with established and start-up companies. Her team manages

a portfolio of 200+ active patent families comprising 700+ patent applications and issued patents worldwide. The team also oversees the institution's interests in over 50 active license agreements.

Dr. Rose is a graduate of the University of Cincinnati and also earned a PhD in Cell and Molecular Biology from the University of Pennsylvania's Medical School and a JD from the Drexel Klein School of Law (inactive status).

Marco Ruella, M.D.
Assistant Professor of Medicine
University of Pennsylvania

Dr. Marco Ruella is an Assistant Professor of Medicine at the University of Pennsylvania and Scientific Director of the Lymphoma Program at the Hospital of the University of Pennsylvania. He is an expert in hematologic malignancies and immunotherapy, in particular CAR T. He has expertise in preclinical CART development and translation to early phase clinical trials, including IND preparation and clinical trial design. He serves as a consultant for several companies and sits on the advisory board of several major biotech-pharma in the space of immunotherapy for cancer. Dr. Ruella is the scientific founder of viTToria biotherapeutics.

Gregory Russotti, Ph.D.
CTO & CMO
Century Therapeutics

Greg Russotti is the Chief Technology and Manufacturing Officer at Century Therapeutics, a company developing iPSC-derived, allogeneic immune cell therapy products for hematology/oncology and autoimmune indications. Century has its first product candidate, CNTY-101, an iPSC-derived NK cell with six gene edits, including AlloEvasion edits, in both a Non-Hodgkins Lymphoma clinical trial and a Systemic Lupus Erythematosus clinical trial. Before joining Century in January 2020, Greg was Vice President of Cell Therapy Development and Operations at Celgene. During his 13 year tenure at Celgene, he guided CMC efforts for five different cell therapy products to IND and clinical stage development. Greg was also a leader in establishing in-house clinical manufacturing at Celgene and in building Celgene's first commercial CAR T manufacturing facility. Prior to Celgene, Greg held various leadership roles at Merck Research Laboratories, developing vaccines and monoclonal antibodies for clinical and commercial manufacturing. Greg received his B.S. and M.S. degrees in Chemical Engineering from Rensselaer Polytechnic Institute and his Ph.D. in Chemical and Biochemical Engineering from Rutgers University.

Aliya J. Sanders, J.D., M.P.H.
Partner
Gunderson Dettmer

Aliya's practice focuses on companies in the life sciences industry and a broad range of emerging growth companies throughout their lifecycles, including their M&A activities. She has significant experience in negotiating licensing and commercial agreements, as well as advising clients on intellectual property protection and strategy, strategic alliances and all aspects of their day-to-day business. Aliya also represents a number of leading venture capital firms in connection with their investments in life sciences and emerging growth companies.

Aliya received her J.D. in 2013 from Columbia Law School, where she was a Harlan Fiske Stone Scholar. She also received a Parker School Certificate in International and Comparative Law from Columbia. While at the law school, Aliya served as the Executive Articles Editor of the Columbia Law Review. In 2013, Aliya also received an M.P.H. from the Mailman School of Public Health at Columbia University, where she focused on health policy and management. Aliya received her A.B. from Princeton University in 2007.

Prior to attending law school, Aliya lived in Cape Town, South Africa for two years, where she worked in curriculum development for mothers2mothers, an international nonprofit organization dedicated to preventing mother-to-child transmission of HIV.

Bob Steinhagen, B.A., cGMP Biopharma Institute
VP, Operations & Life Sciences
ABM

Bob Steinhagen has over 25 years of experience in facility services. As VP of Operations, he leads ABM's Life Sciences industry group, providing innovative solutions to meet the changing needs of Life Sciences manufacturing and research

businesses.

Heather A. Steinman, Ph.D., M.B.A., B.S., B.A.
SVP, Business Development
The Wistar Institute

Heather A Steinman, Ph.D., MBA, is Senior Vice President, Business Development and Executive Director of Technology Transfer at The Wistar Institute, the nation's first independent research institution devoted solely to biomedical science and a world leader in cancer, immunology, virology and infectious disease research. Heather is a member of Robin Hood Ventures, the chair of the Life Sciences Screening Team at Delaware Crossing Investor Group; Advisor on the Healthcare Investment ERC of Ben Franklin Technology Partners, Life Sciences Advisory Board Member of the Philadelphia Alliance for Capital and Technologies, Board Member of BioStrategy Partners, WorldUpstart, and Mid-Atlantic Diamond Ventures and Advisory Council Member of Dornsife School of Public Health.

Shyam Subramanian, Ph.D.
Principal
BioSynth Solutions

Dr. Shyam Subramanian is a biopharma/biotech executive with 20+ years of experience developing CMC strategy and driving program execution from ideation to licensure for innovative medicinal products across modalities. Prior to his most recent venture in consulting, he was Chief Technical Officer at Obsidian therapeutics and built the technical development, manufacturing and quality organization and helped advance OBX-115, the first engineered tumor infiltrating lymphocytes (TILs) cell therapy from concept to promising early clinical data. His career has spanned stints at Merck, Johnson and Johnson and Teva Pharmaceuticals where he has contributed to development, clinical evaluation or licensure & supply of several biologics and vaccines.

Kelly Sullivan, Ph.D.
Director of Labs
CIC Labs + Innovation Campus

Kelly Sullivan serves as the Director of Labs for CIC Labs + Innovation Campus. SHe is an experienced Laboratory Director with a demonstrated history of working in the consumer goods industry. Skilled in METRC, Regulatory Compliance, SOP Development, Method Development, Molecular Distillation, Molecular Biology, and UV/Vis Spectroscopy. Strong research professional with a Doctor of Philosophy (Ph.D.) focused in Biochemistry from Purdue University.

Xiulian Sun, Ph.D.
CTO
uBriGene

As the Chief Technology Officer at uBriGene Biosciences, Dr. Sun brings a wealth of expertise in the cell and gene therapy fields. With a Ph.D. from The University of British Columbia, she stands as a seasoned scientist with notable accomplishments in medicine and biotechnology, particularly in the fields of hematology and cell and gene therapy. Her prolific career is marked by the publication of over 30 academic papers in esteemed journals like PNAS, and the acquisition of 17 invention patents.

Beyond her scientific achievements, Dr. Sun demonstrates remarkable entrepreneurial acumen. She played a pivotal role in the founding of Vigene Biosciences and uBriGene, where she drove forward innovative advancements in cell and gene therapy technologies. Under her leadership, uBriGene achieved significant milestones, securing numerous international patents in areas such as viral vectors, CRISPR gene editing, and pioneering the new CGT delivery modality, mRNA/circRNA RNP.

Gareth Thomas, Ph.D.
Associate Professor
Temple University Lewis Katz School of Medicine

Bachelor's Degree in Natural Sciences, University of Cambridge, United Kingdom PhD with Professor Sir Philip Cohen, University of Dundee, Scotland Postdoc with Dr Rick Huganir, Chair of Dept of Neuroscience, Johns Hopkins Medical School Independent lab since 2011, focusing on mechanisms of neural responses to stress and damage, and in particular roles of the protein-lipid modification palmitoylation in these processes.

Xiaofei Wang, Ph.D.
Clinical Pharmacologist
US Food and Drug Administration (US FDA)

Dr. Xiaofei Wang is a senior clinical pharmacology reviewer in the Office of Clinical Evaluation (OCE), Office of Therapeutic Products (OTP) at the Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration (FDA). She performs clinical pharmacology reviews for Biologics License Application (BLA) and Investigational New Drug Applications (IND) submissions of biological products including cell and gene therapies, blood- and plasma-derived products. Dr. Wang has participated in review of BLAs for multiple novel modalities, including CAR T cell products, AAV-based gene therapies, and ex vivo genetically modified stem cell therapies. In addition to conducting regulatory reviews, Dr. Wang has also actively participated in multiple FDA working groups developing regulatory guidances for drug products, such as guidance for development of CAR T cell products. Prior to joining CBER/OTP, Dr. Wang was a bioequivalence reviewer in Office of Bioequivalence (OB), Office of Generic Drugs (OGD), CDER, FDA. Dr. Wang received her PhD degree in Pharmaceutical Sciences from University of Florida.

Enna Weng, M.B.A.
Managing Director
Freedom Capital Markets

Managing Director of Freedom Capital Markets managing the investment banking business with expertise in equity capital market and venture investing. Prior to joining Freedom, Enna held senior positions in various global financial institutions. She was the Head of U.S. Equity Structured Issuance at Barclays Capitals where she led Barclays to achieve "Best-Selling Product of the Year" and "Best House of US Equities" award. Prior to that, she was managing the Fully Funded Portfolio Risk Trading desk at Wells Fargo and won the "iAward on Innovation". In her earlier career, she also covered Structured Financing at Macquarie USA, and Fixed Income at Morgan Stanley. Her experience includes deal origination, due diligence, and execution across industry sectors on domestic and cross-border transactions. She was also a senior advisor at HELENE BioMed Pte. Ltd where she helped the company at executing an IPO plan as well as cross boarder M&As. She has a breadth of knowledge as an entrepreneur as well as a deep understanding of Capital. Enna holds an Executive MBA degree from Kellogg School of Management at Northwestern University, where she completed executive courses at WHU-Otto Beisheim School of Management in Germany and Hong Kong University of Science and Technology.

Lena Winstedt, Ph.D.
Global Franchise Lead Gene Therapy
Hansa Biopharma AB

Lena Winstedt, Global Franchise Lead Gene Therapy, Hansa Biopharma AB, Lund, Sweden, holds a PhD in Microbiology from Lund University. She has been working with various aspects of drug development in Pharmaceutical and Biotech companies in Sweden and Denmark for more than 20 years. Lena started to work at Hansa Biopharma in 2011 and have been one of the drivers in the development of imlifidase, which in 2020 received a conditional approval in EU as a pre-treatment to remove antibodies prior to kidney transplantation. Lena is now focusing on the development of Hansa's IgG cleaving enzymes for removal of AAV antibodies prior to gene therapy.

Xinqun Wu, M.S.
Sr. Scientist
Bristol Myers Squibb

Irene Wu has been a member of the biotherapeutics bioanalysis group at BMS since 2021, where she supports a variety of therapeutic programs, with a focus on pharmacokinetic (PK) assay development and program troubleshooting.

She has over 16 years of experience in the pharmaceu-

ticals industry, having worked at Schering Plough, Merck, and Celgene prior to BMS. Her expertise is in liquid chromatography-mass spectrometry (LC-MS) and ligand-binding assays (LBA). She is passionate about working to optimize and improve these techniques, along with exploring how they might work together.

Irene received her bachelor in chemistry in 1992 from ShanghaiTech University and a master's in computer science in 2002 from Saint Joseph's University in Philadelphia.

She is also the dedicated mother of two boys. Outside of work, she enjoys playing tennis, fishing, and most of all, learning and spending time with her children.

Bin Xiao, Ph.D., M.D.
Director, R&D
Askbio.inc

Bin Xiao is the Director of Research and Development at AskBio. With over a decade of dedicated service under Xiao Xiao at the University of North Carolina, and three transformative years with Jude Samulski at AskBio, he has garnered a wealth of knowledge and expertise from them. His work focuses on AAV biology, AAV capsid modification, and the application of these advancements to combat a variety of diseases.

Kenneth G. Yancey, Ph.D., M.S.
Executive Director, Process Development and Manufacturing
Upenn Gene Therapy Program

Kenneth is an engineer who is passionate about driving innovation in the area of gene therapy. Since completing his Ph.D in Bioengineering at Cornell University, he has dedicated his career to addressing some of the biggest challenges to gene therapy such as high cost of goods, limited drug access, challenges to insurance reimbursement and challenging commercial models. Kenneth's focus is on process development, manufacturing, analytical and regulatory strategies for the acceleration of clinical and commercial gene therapy applications.

Kenneth's current role is as Executive Director of Process Development and Manufacturing for the Gene Therapy Program at UPENN. He has responsibility for pre-clinical and clinical process development, tech transfer and manufacturing. During his time at GTP, He has overseen the process development and manufacturing of hundreds of unique AAV clinical candidates which have resulted in dozens of clinical programs and successful regulatory applications. He has been involved in driving CMC and regulatory strategy.

Yieyie Yang, Ph.D., J.D.
Partner
Finnegan Henderson

Dr. Yang has a Ph.D. in Molecular Biology and conducted post-doctoral research on breast cancer at Dana Farber Cancer Institute before obtaining a J.D. from George Washington University Law School. During her years of legal practice, Dr. Yang handles complex IP issues in the biotech area, including patent prosecution and patent portfolio management, counseling, due diligence for FTO and M&A, post-grant patent challenge proceedings (including Inter partes review and post-grant review), and complex patent litigation (including biosimilars litigation) before U.S. district courts and the International Trade Commission. Dr. Yang was named by Best Lawyers in its "Ones to Watch" lists for excellence in patent law in both 2023 and 2024.

Hequn Yin, Ph.D.
SVP, Head of Research
Iovance Biotherapeutics

Dr. Yin joined Iovance in November 2021. He is a pharmacologist by training with nearly 30 years of discovery and development experience in various therapeutic areas within the biopharmaceutical industry. His prior leadership roles included Vice President of Oncology Research & Early Development at Pfizer, Executive Director at Novartis, Chief Scientific Officer at Fosun Pharma and President of the Innovation Institute at Qilu Pharmaceutical. Dr. Yin has contributed to the development of Amtagvi, Kymriah and Cosentyx, among others. He earned a Ph.D. in Pharmacology from the University of Rochester and conducted post-doctoral research in the Department of Biochemistry and Molecular Pharmacology at the University of California, San Francisco.

Daozhan Yu, Ph.D.
CEO
AAVnerGene Inc.

Dr. Yu received his PhD degree from University of Maryland at Baltimore in Molecular Medicine. He received post-Doc training and served on faculty at UMB and Temple University. His research covered Diabetes, Obesity, Cardiovascular diseases, iPSCs, disease modeling, drug screening and development, and gene therapy. He holds multiple patents, and drugs that he developed are in clinical trials. In recent years he has been focusing on AAV delivered gene therapy. He was the director at Vigene Biosciences in charge of virus production. In 2019, he Co-founded the company, AAVnerGene Inc with the mission is to develop next generation AAV vectors and processes to increase AAV gene therapy efficiency. With a revolutionary one-plasmid AAV production system, AAVone, it solves AAV production bottleneck problems. With the AI assisted AAV engineering and screening platform, ATHENA, it can increase AAV delivery efficiency and specificity by hundreds of folds, and thus reduce the side effects and cost drastically, making AAV gene therapy accessible and affordable.

Lingzhi Zhao, Ph.D.
VP
NeuShen Therapeutics

I serve as the Vice President VP of Discovery Biology and Head of Gene Therapy at NeuShen Therapeutics, with nearly 20 years of experience in CNS drug discovery. Over the past decade, my main focus has been on advancing AAV gene therapy to tackle neurological diseases

Brian Zhou, Ph.D.
Associate Director, Lilly Venture
Eli Lilly and Company

Brian is trained in immunotoxicology before transitioning into industry as a research scientist focusing on autoimmune disorders. After spending a few years at the bench and in the clinic, Brian transitioned into business development and venture investment.

Track Leads

Lisa B. Baskin, B.S.
SVP, Scientific Real Estate
Scheer Partners

Industry veteran Lisa Berger Baskin has had an impressive and highly diverse 30+ year career in commercial real estate that includes 14 years heading her own commercial brokerage and serving as General Partner for commercial redevelopment projects in the Philadelphia region. Focused on client satisfaction, she has been deeply involved in a wide range of hands-on roles from negotiating complex biotech leases, site selection, consolidations, disposition of assets, to handling zoning and financial analyses. Ms. Baskin is the Broker of Record for Scheer Partners in the State of Delaware, holds a broker license in Pennsylvania and spent six (6) years as Broker and Development of Leasing for an industrial conversion project in the Inland Empire in California. Scheer Partners (www.scheerpartners), is a full service brokerage firm, that is highly regarded throughout the MidAtlantic region as the "go to" firm for scientific real estate. Scheer Partners has built an unparalleled reputation in the biotechnology, pharmaceutical, and lab-related industries for developing effective real estate strategies and solutions to meet the unique needs of these highly specialized companies.

Shuai Dong, Ph.D.
Sr. Manager
Sarepta Therapeutics

Over 10 years of combined academic and industry experience in small/large molecule and cell/gene therapy research and development. Expertise in oncology, rare disease, PKPD, translational research and project leadership from discovery to early development. Excellent communication and management skills with a track record of leadership, team building, and mentoring. Clinical pharmacology for PMOs and gene therapies in rare diseases. Translational PKPD of large molecules including CD3-redirectors, multispecific antibodies, as well as cell/gene therapies including oncolytic viruses, CAR-T/NK, PPMOs. Deep theoretical and hands-on expertise in heme-malignancies, including forward and reverse translation of small molecule kinase inhibitors and immunoregulatory agents. Project team leadership in both large-complexed and small-nimble organizations. Develop, executive strategies and deliver results with minimal guidance from discovery to early development. Hands-on experience with PKPD modeling and simulation using Monolix, Phoenix, NONMEM, and R.

Long Geng, Ph.D.
Sr. Scientist, Clinical Biomarker

Experienced biologics scientist by trainings, with a demonstrated history of working in the pharmaceuticals industry. Skilled at ELISA, MSD, Simoa, Singulex, and Liquid Chromatography-Mass Spectrometry (LC-MS). Strong research professional with a M.S. focused in Bioengineering and Biomedical Engineering from New Jersey Institute of Technology and Ph.D. focused in Biochemical engineering from Villanova University.

Vibha Jawa, Ph.D., FAAPS
Executive Director, Clinical Pharmacology, Pharmacometrics, Disposition & Bioanalysis (CPPDB)
Bristol Myers Squibb

Dr. Vibha Jawa is an Executive Director for Biotherapeutics Bioanalysis in Nonclinical Disposition and Bioanalysis (NDB) organization at Bristol Myers Squibb. Vibha is responsible for leading biotherapeutic and cell /gene therapy bioanalytical (BA) function supporting DMPK and immunogenicity, and provide strategic and scientific oversight for BMS developmental portfolio. Vibha was at Merck for 4 years where she lead the Predictive and Clinical Immunogenicity group and at Amgen for 14 years supporting Discovery to Development for biotherapeutics. Vibha has 20+ years of experience in diverse fields of biologics , vaccine development and gene therapy with successful support of 20 + IND, BLA and MAA filings. Vibha is a recognized leader in Bioanalysis and Immunogenicity with 75+ peer-reviewed publications and serves as a Reviewer and Editor for The AAPS Journal and J. Pharm Sci. She is an active member of multi-

ple scientific societies and consortiums (IQ, SC space Consortium and EIP) .Within AAPS, she is Track Chair of Land O Lakes Bioanalysis Meeting, Chair of the Cell and Gene therapy Bioanalysis and Biomarker working group , Steering Committee member of the Therapeutic Product Immunogenicity Community, past chair of Immunogenicity Risk Assessment and Mitigation Community and leads the IQ Consortium for Cell/Viral/Gene therapies. She was recognized as the AAPS Fellow 2022. Vibha is the President of Steampark a non profit promoting STEM based learning in underserved communities. She also likes to mentor high school students on STEM related projects and early career scientists in her free time.

Bill Lu, M.B.A.
Principal Consultant
Forerun Advantage

Bill Lu is the founder and principal Consultant of Forerun Advantage. He helps Chinese biotech companies to understand US business culture and biotech ecosystem, establish business operations, and connect with investors, academics, business leaders, government officials, etc. Before moving into biotech business consulting, he spent 13 years in Emory University School of Medicine leading efforts to optimize medical resource utilization with Real-World Data (RWD). He also built a clinical trial data management system for NIH-sponsored clinical trials, as well as software for a helmet-based sport sideline assessment of concussions and mild cognitive impairments. Bill has volunteered at SAPA-GP since 2019 and currently serves as head of PR for SAPA-GP.

Bill graduated from Peking University in 1984 with a BS in Biochemistry. He spent the next five years in Beijing Medical University (later merged into Peking University) teaching molecular genetics. In 1988, Bill was selected to participate in the prestige CUSBEA (China–United States Biochemistry Examination and Application) program and came to the US in 1989. He earned MS in Molecular Biology from Vanderbilt University, MS in Computer Information Systems from Kennesaw State University, and MBA from Emory University.

Yixuan Ming, Ph.D.
Scientist
Spark Therapeutics

Yixuan is a scientist at Spark Therapeutics. He earned his Ph.D. in Electrical Engineering at Lehigh University. Before joining Spark, he spent one year as postdoc researcher in Biomedical Engineering at Washington University in St. Louis.

CJ (Chunjuan) Song, Ph.D.
VP
Exegenesis Bio

Dr. CJ (Chunjuan) Song, PhD, DABT, is Vice President of CNS Disease Research and Pharmacology & Toxicology at Exegenesis Bio. CJ has been a Certified Diplomate of the American Board of Toxicology since 2018 and possesses more than 10 years of experience in the gene therapy field and over 15 years in preclinical translational work. Prior to her current role, CJ worked as a Research Director at the Gene Therapy Program (GTP), University of Pennsylvania, where she led and supervised a team of scientists working on translational research aimed at developing potential therapeutics for life-threatening diseases utilizing AAV-directed gene therapy. She had worked at Applied Genetic Technologies Corporation (AGTC), where she led a team in Target Validation and In Vivo Pharmacology and Toxicology. CJ earned a B.S. in Biology from Nankai University and a Ph.D. degree from Iowa State University with co-majors in Genetics and Neuroscience. Afterwards, she completed a postdoctoral fellowship in the University of Florida, where she conducted research on age-related macular degeneration and neuroinflammatory diseases. Dr. Song has published over 30 peer-reviewed research articles and chapters in the field's preeminent journals and has served as an editor, guest editor, and reviewer for a list of reputable journals.

Mitra Tavakkoli, M.D., Pharm.D.
Sr. Clinical Consultant
Independent Sr. Clinical Consultant

Experienced Clinical Development physician with more than 12 years of experience in early and late phase development in gene therapy, cell therapy and rare diseases. • Former Internal Medicine Therapeutic Area Head at Spark Therapeutics • Former VP of Clinical Development at Avro Bio • Former Head of Neurodevelopment Disease and Genetic epilepsies at

Taysha Gene Therapies • Former VP of Clinical Development at 4D Molecular Therapeutics • Rare Disease Gene Therapy Consultant: Academia and Industry

Huize Yan, M.S.

Process Development Scientist
Spark Therapeutics

Huize is the Upstream Process Development Scientist at Spark Therapeutics, a member of the Roche Group. Prior to Spark, Huize had worked at WuXi Advanced Therapies, a global CDMO for cell and gene therapy, leading multiple viral vector manufacturing projects including a commercial product (Lentivirus for Breyanzi®) and also Adherent 2.0 platform development. She earned the master's degree from Columbia University with research background on non-viral gene delivery and nanodrug system for immune diseases. Huize has been an active member of SAPA-GP community and served as the co-lead of Entrepreneurship Session in 2022 CGT conference and the Track lad for the CMC Track. This year, she continues to serve as the track lead for the CMC Track.

Session Chairs

Matt Cabrey, B.A.
Director
Ideas x Innovation Network (i2n)

A strategic, innovative leader who inspires creativity and action, Matt Cabrey (Kay-Bree) has established a record of successes over a diverse career in the nonprofit, biopharmaceuticals, financial services, business, media, and public relations sectors. As a results-oriented executive with regional, national, and global experience, Matt's positive approach delivers solutions for complex issues through business and communications strategies. Matt has traveled to more than 60 cities in 18 countries, helped to open business operations and supported business growth in three countries, organized and hosted numerous international business delegations, and developed and implemented dozens of community engagement projects. As Director of the Ideas x Innovation Network (i2n), Matt Cabrey (Kay-Bree) leads the team of highly engaged staff and volunteers who are helping startup companies, entrepreneurs, and innovators from across southeastern Pennsylvania – and nationally and globally – transform their ideas from concept to commercialization. Matt is responsible for overall management of i2n, including engagement of our i2n Partners, which consists of corporate, university, business, civic and community organizations; and our i2n Entrepreneurs, which consists of early-stage startups as well as established creators and innovators, primarily in the Tech and MedTech sectors. He is also an entrepreneur, having founded Growing Greater LLC, a strategic business growth and communications advisory firm. Matt created and co-produced the Emmy-award winning television show Growing Greater Philadelphia with NBC10, and more than 150 episodes of the Growing Greater podcast. Matt previously led Select Greater Philadelphia, a regional business attraction marketing organization focused on growing the economic vibrancy of the 11-county community by attracting new businesses, jobs and talent. He has held roles with Shire plc, PNC Bank, Keystone Mercy Health Plan, the American Red Cross, and CBS Radio. A frequent speaker, moderator and advisor, Matt has appeared on numerous media outlets discussing topics ranging from business growth and economic issues to clinical trials and pharmacovigilance, and more.

A graduate of Penn State University, Matt earned a BA in journalism with a minor in sociology. He has traveled to more than 60 cities in 18 countries, supported business operations and growth in three countries, and has organized and hosted numerous regional, national and international business initiatives and delegations. A proud native of Philadelphia's Overbrook neighborhood, Matt and his family live in Chester County, PA.

Zhiyi Cui, Ph.D.
Associate Director, DMPK Modeling
GSK

Zhiyi Cui earned her Bachelor of Science degree in Biomedical Engineering from the Sichuan University in China and a doctorate degree in Pharmaceutical Sciences from the University of Houston in 2015 focusing on pharmacokinetics/pharmacodynamics (PK/PD) in pregnant sheep model. She is currently working as a PBPK/PD modeler in DMPK modeling group of GSK (Collegeville, PA, USA) for discovery projects support in multiple therapeutic areas including Immunology, Oncology and Infectious Disease. Prior to her current role at GSK, she was a Senior Scientist in the Translational Modeling & Simulation group at AbbVie (North Chicago, IL, USA) where she supported oncology programs in discovery and early development as a DMPK representative and a modeling scientist. Zhiyi has extensive pharmaceutical industry experience specializing in translational PKPD and PBPK modeling. She is a current member of the American Association of Pharmaceutical Scientists (AAPS) and Target Protein Profiling Working Group at IQ Consortium.

Jake Dong, Ph.D.
Scientist, Cell Therapy
Johnson & Johnson Innovative Medicine

Dr. Guangyu (Jake) Dong is a CAR-T Scientist at the Cell Therapy Department of Johnson & Johnson Innovative Medicine Research and Development, LLC. He is currently working on developing next generation iPSC derived allogeneic CAR-T cell therapies. Dr. Dong has over seven years of biopharmaceutics industrial experience on drug discovery and development at Janssen Research and Develop-

ment, LLC (JNJ) supporting and contributing to JNJ biotherapeutics pipelines including TREMFYA®, STELARA®, nipocalimab, RYBREVANT® (EGFRxMET), TECVAYLI® (CD3xBCMA) and CARVYKTI ®, etc. Previously, Dr. Dong has seven years research experience at University of Pennsylvania where he was lab manager and associate faculty. His research interest was focused on transcriptional regulation of inflammation in innate and adaptive immune response. Dr. Dong received his PhD degree in T cell biology from Ben-Gurion University, Israel and conducted his postdoctoral training in Immunology at University of Pennsylvania. He served as Scientific Discovery track lead in SAPA-GP AC2024 (Annual Conference).

Austin Duke, Ph.D.
Managing Director
BroadOak Capital Partners

Austin Duke is a Managing Director at BroadOak where he primarily leads and supports the firm's venture capital and early-stage investments. Prior to joining BroadOak, Austin led healthcare venture capital investments for UnityPoint Health Ventures. He has led investments and served on the board of directors for a diverse set of companies operating across healthcare sectors. Previously, Austin served as Chief Science Officer for a neuromodulation company.

Yu-Chih Hsu, Ph.D.
Director, Bioassay Development and QC
UPenn GTP

Jay serves as a director of the bioassay development and QC at Gene Therapy Program in UPenn. His recent studies focused on different bioassay development in analytical science department for stability and release testing. In UPenn, he developed a cell screening system to identify a suitable cell line for each serotype to improve AAV transduction rate. Prior to joining GTP, Jay spent one year and six years at Wuxi and GSK on multiple analytical science projects including bioassay development for small molecules and antibodies, automated bioassay, immunoassay development and validation. He completed his postdoc training in Eli Lilly and Company and received his Ph.D. in biochemistry at SUNY, Buffalo.

Sima S. Kulkarni, J.D., M.S.
Special Counsel
Duane Morris

Sima concentrates on intellectual property law, focusing on patents, trademarks, copyrights and trade secrets. She counsels clients in all aspects of IP matters, including strategic IP portfolio development, patent prosecution, trademarks, licensing and commercialization. Her clients include biotech, healthcare, life science and pharmaceutical companies ranging in size from emerging growth and start-ups, to multinational global corporations and academic institutions. Prior to working as an IP attorney, Sima worked at the Ronald McDonald Cancer Research Center in the Pediatric and Hematology Laboratory, utilizing molecular biology and protein purification techniques to identify antigenic markers.

Sima specializes in patent prosecution, from drafting to examination. She works closely with inventors to optimize coverage for inventive technologies, focusing on both broad and nuanced aspects of the invention's novelty and nonobviousness. She develops prosecution strategies that enable uniform argumentation across international patent offices, and coordinates patent coverage to accurately correspond to the ultimate commercial product as it advances from R&D stages to the marketplace. She also assists clients with transactions such as MTAs, tech transfer, and joint development agreements involving IP.

Sima obtained her Law degree from the University of Georgia School of Law, her Master's degree in Biology from Georgia State University, and her Bachelor's degrees in Biology and Philosophy from Emory University. She is a frequent speaker on topics related to intellectual property and the life sciences industry with a focus on cell and gene therapy. In Spring 2024 Sima was selected to the Metro Philadelphia AAPI Power Players List.

Yan G. Ni, Ph.D.
Executive Director
Passage bio

Dr. Yan Ni is an Executive Director of Biomarkers and Precision Medicine at Passage Bio. The Biomarkers and Precision Medicine team is responsible for the overall biomarker strategic planning and execution for all clinical and preclini-

cal programs in the Passage Bio drug development portfolio. Before Passage Bio, Yan was an Associate Director at the Precision Medicine Group of Regeneron Pharmaceuticals and was responsible for clinical biomarker planning and implementation for multiple disease areas from First-in-human to phase III. Yan also worked in the BioAnalytical Sciences Department at Bristol-Myers Squibb for five years, where her team provided biomarker assay development, validation, and outsourcing support for the clinical pipeline. Her industry career started at Merck Research Laboratories at Rahway, New Jersey.

Yan actively volunteers for the American Association of Pharmaceutical Scientists (AAPS) and is a co-founding member of the AAPS Biomarkers and Precision Medicine Community and the Gene and Cell Therapeutic Product Communities. She is an inventor of several patents and is recognized for her expertise in clinical biomarker development and translational science. Yan receives her PhD in Neuroscience from University of California, Irvine, and holds a Master of Science degree from the Institute of Basic Medical Sciences in Beijing.

Jingwen Niu, Ph.D.
Principal Investigator
AlphaThera

PhD in Cell Biology and Developmental Neuroscience, with a professional background in Spinal cord development, AAV gene therapy, injury and neurodegeneration & regeneration, etc.

Marcia Z. O'Connor, M.S.
CEO & Founder
The O'Connor Group

Marcia Zaruba O'Connor is the CEO and Founder of The O'Connor Group, a leading provider of Outsourced Human Resources and Talent Acquisition solutions based in King of Prussia, PA, Raleigh NC and soon Tampa, FL.

The O'Connor Group started in 2007 and currently has over seventy-five employees around the country. Our main areas of focus are the Professional Services, Life Sciences/Healthcare, Information Technology and Manufacturing sectors.

In 2022 alone, The O'Connor Group was fortunate to be the recipient of the Inc. 5000 Fastest Growing Businesses, The Philadelphia Business Journals' Best Places to Work and Most Admired CEO awards, The Inquirer's Soaring 76, Philadelphia Titan 100, and the Entrepreneurs Forum Philly 100 awards.

Currently, Marcia is the President for the Entrepreneur Organization, Philadelphia Chapter. The O'Connor Group is also a Certified Women's Business Enterprise.

Marcia loves helping entrepreneurs and in 2023 rolled out a new initiative specifically geared to start up female entrepreneurs called Shadow Her.

Bryan Tsao, Ph.D.
Manager, Life Science & Healthcare Initiatives
Chamber of Commerce for Greater Philadelphia

Bryan's role at the Chamber of Commerce for Greater Philadelphia aims to support and grow the life sciences ecosystem through regional economic development. Bryan has 10 years of academic research experience in cancer biology. After graduating with a Bachelor's in Cell Biology from University of Kansas, Bryan obtained his Ph.D. in Biomedical Sciences from Penn State University College of Medicine in 2020. His thesis focused on the roles of DNA polymerases and the mechanisms of carcinogenesis during oncogene activation. As a postdoc at Rutgers New Jersey Medical School, he studied the various tools used during analytical development of cell therapies. For this work, he received a NSF award for the National I-Corps training program and learned about entrepreneurship and business development in the industry. He also works as the Program Director for BioStrategy Partners, an academic consortium that aims to enable commercialization of academic inventions. He manages a practical knowledge series panel on commercialization, acts as one of the Coordinator for the Keystone Innovation Zone tax credit program, and administers a small-scale grant funding program to de-risk early-stage technologies.

Lili Wang, Ph.D.
Former Research Director
University of Pennsylvania

Dr. Lili Wang is a research associate professor and a re-

search director at the Gene Therapy Program at the University of Pennsylvania. She has been in the field AAV gene therapy for over 25 years with extensive experience in the development of in vivo gene therapy for rare genetic diseases, including vector design & vector optimization, preclinical vector production, in vivo gene therapy in small and large animal models. Several of the preclinical programs she led have advanced to phase I - III clinical trials. Over the past 8 years, she has expanded her research interest to in vivo genome editing with CRISPR/Cas9 and meganuclease and demonstrated efficacy of in vivo genome editing/gene targeting as novel treatment approaches for liver metabolic diseases in mouse models and nonhuman primates. In her talk, she will discuss her work on developing AAV gene therapy and in vivo genome editing to treat metabolic diseases in liver, such as OTC deficiency.

Michele Washko, M.B.A., M.A.
CEO
Life Sciences Greenhouse Investments

Michele Washko served as Vice President, Strategic Services, for Life Sciences Greenhouse Investments (LSGPA.com) from 2005 until 2015 and returned to the organization in 2022 to take on the role of President and CEO. In the interim, she worked for Geisinger Health System's Institute for Advanced Application; founded Life Science Innovations, a boutique consulting firm; and served as COO, then CEO, of Respana Therapeutics, Inc. Ms. Washko holds a BA from Emory University, and an MBA from Penn State University.

Xinjun Zhang, Ph.D.
Associate Principal Scientist
Merck

Xinjun Zhang currently is an Associate Principal Scientist in Neuroscience Discovery Department at Merck. Since joining Merck in 2018, he has worked on identifying and validating new drug targets for neuropsychiatric and neurodegenerative diseases, developing novel electrophysiological and molecular platforms to support neuroscience drug discovery. He is also a lead at Merck West Point LINK (Leveraging Internal Networks & Knowledge) team. Xinjun was a research associate at Memorial Sloan-Kettering Cancer Center previously. His research focused on studying the functional connectivity and organization during neural development. He has published more than 18 research papers in top-tier journals. Xinjun received his PhD in neurobiology from Fudan University. Xinjun is also an enthusiastic volunteer serving multiple organization to plan and coordinate events on pharmaceutical science and healthcare communications among different institutions. He led the SAPA-GP 2024 Annual Conference.

Ying Zhou, Ph.D., M.B.A.
Analytical Program Steward
Teva Pharmaceuticals

Ying is an experienced analytical project manager within the Biologics CMC organization at Teva Pharmaceuticals. She started her career as a Ph.D. research scientist, interfacing between a matrix team of analytical scientists and internal clients in Biologics CMC to ensure timely data/analytics delivery. Her responsibilities have since expanded to regulatory filings (US, EU, and international markets), cross-functional technical collaboration within and outside CMC, CMC stage gate development/execution, international technology transfer, and vendor management. Ying also sits in the joint CMC team for several partnership products/projects and provides analytical expertise to support these partnerships.

Peixin Zhu, Ph.D.
VP, Editing Development
Verve Therapeutics

Peixin is the VP of Editing Development of Verve Therapeutics (NASDQ: VERV); Peixin was the VP of R&D of Tevard Biosciences; VP of Discovery Research of LogicBio (NASDQ: LOGC, now AstraZeneca). Prior to the above roles, Peixin Zhu led multiple teams at the Novartis Institutes for Biomedical Research; Applied Genetic Technologies Corp. (NASDQ: AGTC; now Syncona); and Exegenesis Bio Inc.

Leadership Team

Lu Wang, Ph.D., M.B.A., P.M.P.
Director
Spark Therapeutics

Lu is the Director of CMC Process Development in the Technology Development organization at Spark Therapeutics, where she worked since 2020. Prior to joining the Spark team, she accumulated 10 years of experience at Teva Pharmaceuticals and Bristol Myers Squibb. After earning her Ph.D. in Biochemical Engineering from McMaster University in Canada, Lu also expanded her expertise by working at the Pacific Northwest National Laboratory. In 2020, she obtained her MBA from Penn State University, further augmenting her strategic leadership skills.

Lu has been an active volunteer with the Sino-American Pharmaceutical Professionals Association - Greater Philadelphia (SAPA GP) since 2017. She has served on the organizing committee of the annual conference, hosted conference sessions, and transitioned to lead the Cell and Gene Therapy (CGT) section in 2021. Additionally, she has been elected as the President-elect for the 2025-2026 term.

Yufeng Li, Ph.D.
Director, Clinical Scientist
Vivace

Yufeng Li, PhD, serving as Director of Clinical Science at Vivace Therapeutics based in Philadelphia, PA. Yufeng graduated from Shanghai Jiao Tong University, and obtained PhD training at UT MD Anderson Cancer Center at Houston, focusing on cancer immunology and immunotherapy. Subsequently, he spent many years at GSK to discover and develop medicines for cancer patients. Prior to Vivace, Yufeng has also served other biotech companies (Ascentage, Transcenta, Qilu Pharma) to oversee their US and global clinical programs.

Yufeng is active in community-based volunteer activities, including serving important roles in organizations such as Sino-American Pharmaceutical Professionals Association – Greater Philadelphia (SAPA-GP). He has established the Pharma360° training program. Yufeng is the president elected for SAPA-GP for 2024-25 term.

Tao Niu, Ph.D.
Director, Quantitative Clinical Pharmacology
Sarepta Therapeutics

Tao Niu has extensive experience in clinical & quantitative pharmacology for rare genetic diseases, particularly in viral and non-viral in vivo gene therapy. He is currently a director of quantitative clinical pharmacology (QCP) at Sarepta Therapeutics and leads the QCP efforts for ELEVIDYS (delandistrogene moxeparvovec), the first and only approved gene therapy for Duchenne Muscular Dystrophy. Prior to Sarepta, Tao held positions with increasing responsibilities at Vertex Pharmaceuticals, Pfizer, and Merck. He represents Sarepta Therapeutics in the IQ consortium clinical pharmacology leadership group, immunogenicity working group, and nucleic acid working group. Tao holds a PhD in pharmaceutics from University of Houston, an MS in pharmacometrics from University of Maryland.

Fang Shen, Ph.D.
VP, Target Biology
Immunome

Fang Shen, PhD, has more than 15 years of industry experience in drug discovery and translational research. Fang currently served as VP of Target Biology at Immunome, where he leads biology team to identify and understand tumor associated antigens as novel targets to treat cancers. Before joining Immunome, he was Associate Scientific Director at Janssen R&D, where he led a cross-coast research team to develop novel therapeutics to treat autoimmune diseases and cancer. Prior to Janssen R&D, he had a successful career in the Immunology Department at Genentech. Fang earned his PhD in Immunological Pharmacology at Peking Union Medical College & Chinese Academy of Medical Sciences in China. He then performed post-doctoral work at Dr. Sarah Gaffen's lab in the University of Buffalo, where he contributed to decipher IL-17 function and IL-17 receptor signal transduction.

Saisi Xue, Ph.D.
Principal Scientist, Drug Product Development
Bristol Myers Squibb

Saisi Xue is a seasoned technical lead with years of industrial experience in Analytical R&D, cGMP, and CMC for chemical and biological molecules in multiple dosage forms. Her current role is the Principal Scientist at Bristol Myers Squibb, where she serves as a drug product analytical lead in the Oral Product Development team. Before joining BMS, Saisi worked in Novelstar pharmaceuticals, where she led end-to-end analytical research and development, GMP support and IVIVC modeling for several 505(b)(2) and ANDA products, and supported CMC regulatory filings. Before Novelstar, Saisi worked in the CMC division of Frontage Laboratories. Saisi received her Ph.D. in Chemical Engineering from Michigan State University. Her research focused on understanding the plant cell-wall recalcitrance to improve lignocellulosic biorefinery by characterizing non-cellulosic carbohydrates and lignin-derived metabolites structures.

Yang Yuan, Ph.D.
Associate Director
Jazz Pharmaceuticals

Yang Yuan is Associate Director in Nonclinical Research& Development at Jazz Pharmaceuticals. She works as a nonclinical team lead in global drug discovery and development team. She also serves as Subject Matter Expert on Due Diligence teams at Jazz Pharmaceuticals. Prior to joining Jazz, she worked as Senior Principal Scientist at Bristol Myers Squibb and DuPont/FMC as technical leader in global regulatory sciences group with increasing responsibilities. Yang has received her Ph.D. in medicinal chemistry from College of Pharmacy, University of Illinois Chicago. Yang is currently pursuing MBA for executive at the Wharton School, University of Pennsylvania. She also holds a MS in Pharmacometrics from University of Maryland. She has served SAPA-GP President in 2023-2024.

Advisory Committee

Haichen Yang, M.D., M.B.A., M.A.
VP, Clinical Research
Amicus Therapeutics

Dr. Yang is the Co-chair of the Advisory Committee for the 2024 Philly CGT Conference and a former SAPA-GP President (2022-23). She is an accomplished pharmaceutical executive with 30 years of experience in neurology, psychiatry, pain, and metabolic disorders. She has led successful global clinical development programs, resulting in new drug and indication approvals, including Fycompa®, Keppra®, and Luvox CR®.

Dr. Yang is Vice President of Clinical Research at Amicus Therapeutics, overseeing small molecule and gene therapy clinical programs. Previously, she was Vice President at ICON plc, providing strategic consulting, acting as Chief Medical Officer, and conducting due diligence for investors. She has also worked for Eli Lilly, Solvay, UCB, and Eisai.

Dr. Yang has authored 2 book chapters, 40+ peer-reviewed articles, 120+ conference posters, and several industry articles. She is a frequent speaker, holds committee memberships in multiple drug development societies, and is a board member of a US investment firm. Dr. Yang earned her medical degree from Peking University, a Master in molecular biology from Indiana University, and an MBA from Temple University Fox School of Business.

Jing Yang, Ph.D.
Chief Scientific Officer
BaseCure Therapeutics

Jing Yang, PhD, Chief Scientific Officer, Founder and Board Director, BaseCure Therapeutics Jing is currently the CSO, Founder and Board Director of BaseCure Therapeutics. She is responsible for the development and execution of business plan and plays a key role in business partnership and fund raising of the company. Within 2 years, Jing led the development of proprietary siRNA platform technologies and rapid progression of the research pipeline to IND stage. Previously served at Centocor, J&J and Bristol Myers Squibb for over 21 years, Jing is recognized as an accomplished drug hunter with extensive experience leading cardiovascular discovery research teams. Her expertise spans from small molecules to biologics and stem cells. Jing also held a number of leadership roles in Corporate and Non-Profit Organizations, most notably serving as Board Member of SAPA (2024), Global Lead of Pan Asian Network at Bristol-Myers Squibb (2019-2021) and President of SAPA-GP (2019-2020).

Jim Fendrick, B.S.
President & CEO
Rockland Immunochemicals

With over 30 years of experience in the biotechnology industry, I currently lead Rockland Immunochemicals, Inc. as the President & CEO and chairman of the Board of Directors for the organization. Throughout my tenure, I have led the company in its growth as a global biotechnology company that specializes in life science research tools and contract research services, positioning Rockland as a leading expert in antibody and assay development.

Rockland is a global biotechnology company focusing on life science research tools and contract research. Rockland conceives and produces reagents involved in cancer and other molecular signaling pathways, which are incorporated into immunoassays for the detection of biomarkers for various diseases. Partnering with leading government, academic, and biopharma institutions throughout North America, Europe, and Asia is a cornerstone of Rockland's success.

Frederick Jones, M.D., M.B.A.
Partner
BioAdvance

Dr Jones has over 30 years of experience as an academic physician, biopharma executive and venture investor. He has served on the boards of numerous companies. He is currently a Partner at BioAdvance, an early stage biotech venture investor focused on the Mid-Atlantic region.

Operating Committee

Namila FNU, Ph.D.
Scientist, Downstream Process Development
Spark Therapeutics

Namila is a Downstream Process Development Scientist at Spark Therapeutics. Namila obtained her PhD in Biomedical Engineering from the University of Arkansas. Before joining Spark Therapeutics, she worked at Wuxi Biologics Vaccine Downstream process development.

Yifan Gong, M.S.
PhD student
Temple University

Yifan is a doctoral candidate at School of Pharmacy, Temple University. His skills include animal in vivo study, drug metabolism, ADME, Mathematical Modeling, and LC-MS. Yifan obtained his Master of Science from Temple University.

Dian He, Ph.D.
Associate Professor
Holy Family University

Education: Ph.D, Organic Chemistry, The Ohio State University; MS, Analytical Chemistry, Marshall University; BS, Chemistry, Zhongshan University. Research Interests: Molecular Dynamics

Shuo Huang, Ph.D.
Scientist II
Carisma Therapeutics

Dr. Shuo Huang, as Scientist II at Carisma Therapeutics, plays a pivotal role in advancing projects centered on mRNA/LNP in vivo CAR-M therapy for metastatic solid tumors. These endeavors stem from collaborative efforts between Carisma Therapeutics and Moderna. Dr. Huang spearheads the utilization of multicolor flow cytometry readouts, crucial for assessing CAR expression, immune cell composition, and cell phenotypes and functions. Moreover, she is instrumental in developing diverse in vivo tumor models to showcase efficacy and actively contributes to IND studies. Dr. Shuo Huang obtained her Ph.D. from the Pathobiology and Molecular Medicine graduate program at the University of Cincinnati, where her research delved into elucidating the function of myeloid cells in combating fungal infections using mouse models.

Haichen Nie, Ph.D.
Associate Director
Teva Pharmaceuticals

Haichen Nie works for Teva Pharmaceuticals as an Associate Director, leading a team that develops formulations for biologic drug products and evaluates the application of novel excipients in various dosage forms. Before joining Teva, Haichen worked at Merck & Co. and AbbVie Inc., focusing on formulation and process development. He received his Ph.D. from the Department of Industrial and Physical Pharmacy at Purdue University and possesses extensive experience in preclinical development, formulation and process optimization, and commercial manufacturing.

Specializing in physicochemical characterization, spectroscopic analysis, and the development of oral and sterile drug products, Haichen has authored over 35 peer-reviewed publications in pharmaceutical journals and has been granted several patents, starting in 2016. Haichen also works as an adjunct Associate Professor at Purdue University College of Pharmacy, teaching both PharmD and PhD students on dosage forms, physical pharmacy, and pharmaceutical solids.

As a volunteer, he is an EO member of SAPA-GP, leading outreach and engagement efforts. He serves as a member of the Editorial Advisory Boards of AAPS PharmSciTech, Drug Development and Industrial Pharmacy, and the Journal of Pharmaceutical Sciences. In addition, he is an expert committee member for the US Pharmacopeia and has served as the chair of the AAPS excipient community since 2021. In 2023,

Haichen received the IPEC Henk De Jong Industrial Research Achievement Award in Excipient Technology in recognition of his contributions to excipient technology and the innovative use of excipients in pharmaceutical sciences.

Patricia Y. Tsao, Ph.D., M.D.
Chief Operating Officer and Scientific Director
CytoEX Inc.

Patricia Tsao, MD, PhD is the Chief Operating Officer and Scientific Director of CytoEX Inc., a Contract Research Organization specializing in Flow Cytometry.

A crucial part of her responsibilities includes overseeing the operation and research efforts to meet both scientific and strategic standards. This encompasses flow cytometry project planning consultations, sample preparation, panel design, surface and intracellular staining, bulk or single-cell sorting, and data acquisition, analysis, and interpretation.

An immunologist with over 25 years of experience in basic, translational, and clinical research, Dr. Tsao's expertise extends to overseeing operations at a startup CRO, a university Immunology Core facility, a Rare Disease Research Center, and CAR T Cell Therapy and Autoimmunity research laboratories. Her demonstrated success includes increasing revenue, eliminating deficits, and generating profits. She excels in setting up new facilities and managing effective day-to-day operations. Well-regarded by colleagues, clients, and employees, her leadership approach involves shaping and aligning with the organization's vision, paying meticulous attention to detail, and maintaining a commitment to operational excellence, driving both scientific progress and organizational success.

Hui Wang, Ph.D.
Head, US Business Development
Genevoyager

Hui is the Head of US Business Development at Genevoyager. Hui has been the co-chair, business development of SAPA-GP since 2012. She obtained her Ph.D. from The University of Edinburgh.

Ruixi Wang, Ph.D., M.S.
Scientist
Spark Therapeutics

Ruixi is a Downstream Process Development Scientist at Spark Therapeutics and Instructional Associate for Introduction to Quantum Computing at Georgia Institute of Technology. He earned his Ph.D. in Chemistry at Wayne State University, and M.S in Computer Science at Georgia Institute of Technology.

Sherry Wang, M.S.
Logisitics Lead
SAPA-GP

A long time volunteer with SAPA-GP for more than a decade, currently leading the logistics function in the organization

Jin Wen, Ph.D.
Sr. Scientist
Spark Therapeutics

Jin is an accomplished technical lead with extensive industrial experience in Analytical CMC for biological molecules and AAV. Currently, she is a Senior Scientist at Spark Therapeutics, where she leads the development of mass spectrometry methods, supporting AAV process development, product characterization, tech transfer, and regulatory filings. Before joining Spark, Jin was a Mass Spectrometry Subject Matter Expert and Analytical Development Project Lead at Teva Pharmaceuticals. She earned her Ph.D. in Chemistry from The Ohio State University, specializing in designing combinatorial peptide libraries for drug discovery and cyclic penetrating peptide design for intracellular delivery.

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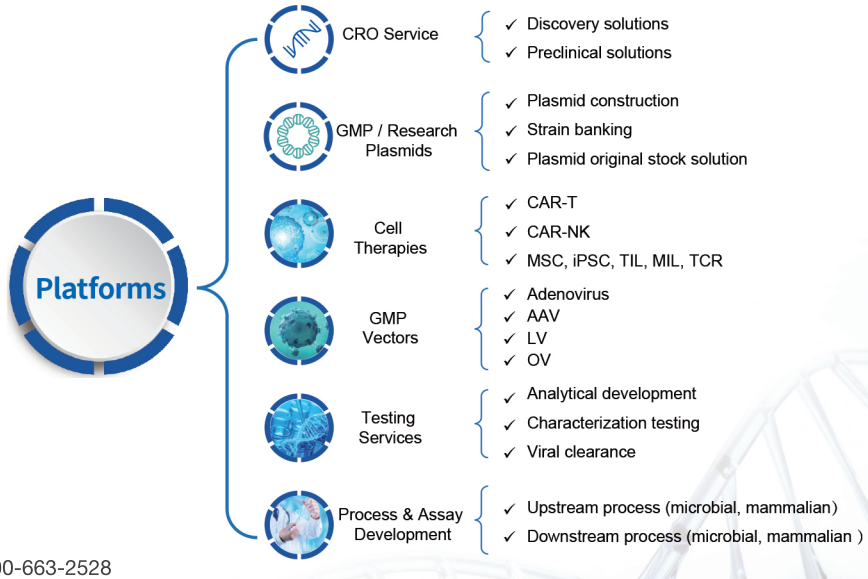

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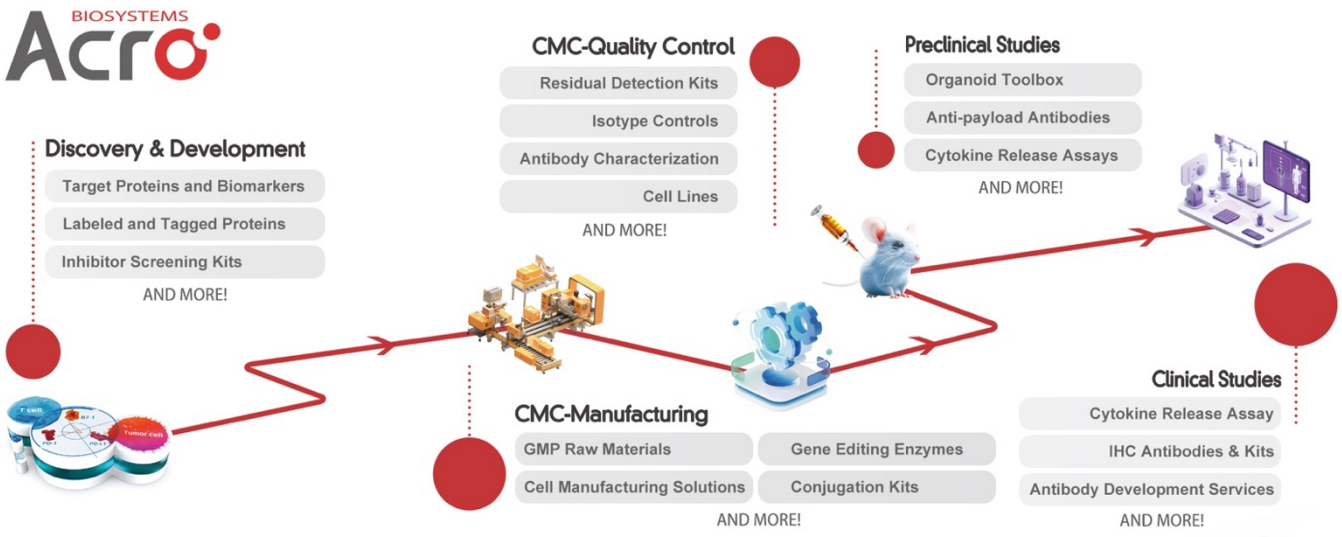

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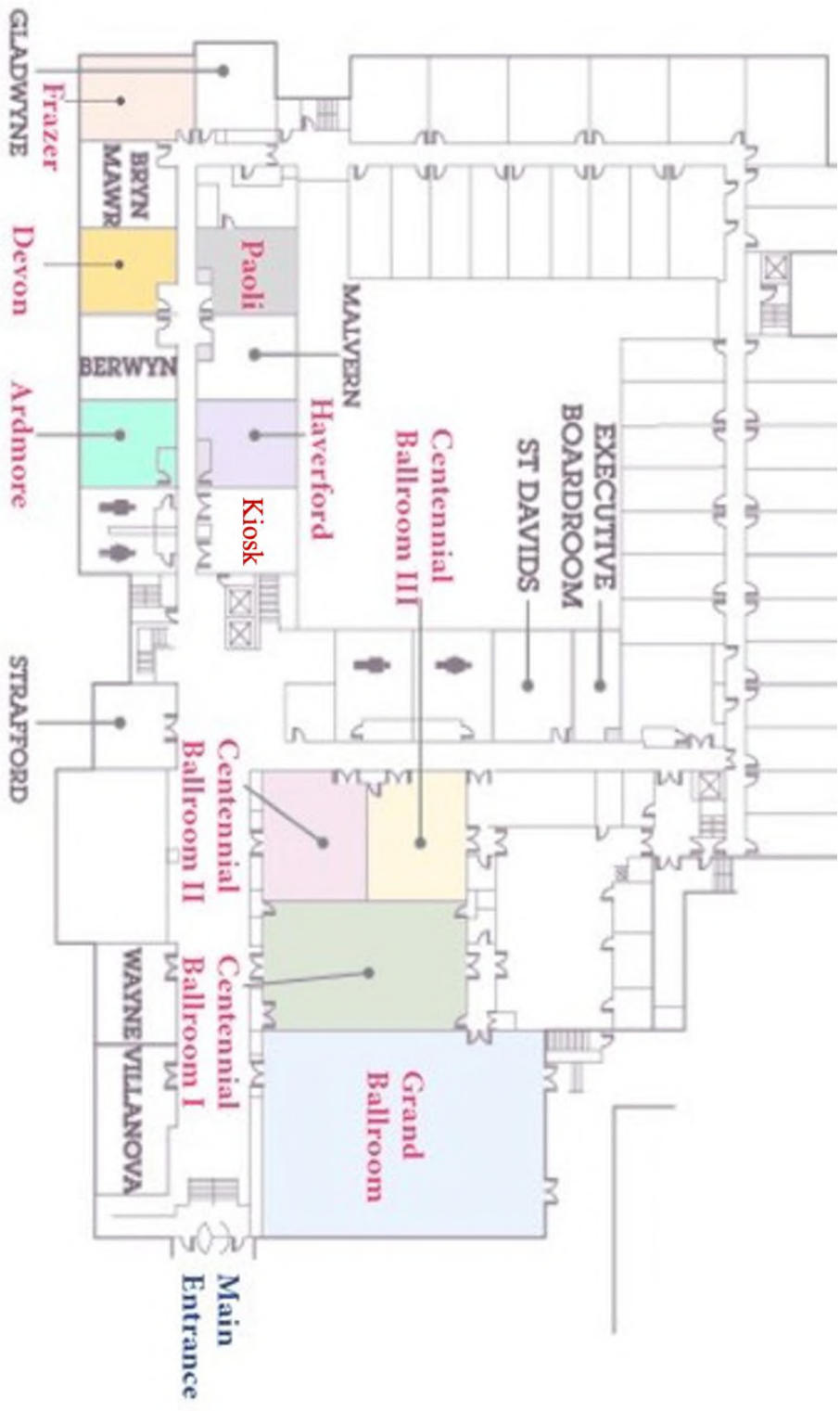

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