2024 SAPA-GP Annual Conference

Friday, March 8th &
Saturday, March 9th, 2024

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

Innovating Biopharma Frontier

A Path to Growth and Impact

For sponsorship opportunities, please contact: bd@sapa-gp.org

SAPA 美中藥協 Philadelphia 費城 sapagp.org

A WELCOME LETTER FROM CONFERENCE CO-CHAIRS

Dear SAPA-GP Members, Volunteers, and Friends,

We warmly welcome you to the 2024 Annual Conference of the Sino-American Pharmaceutical Professionals Association – Greater Philadelphia (SAPA-GP)! This gathering stands as another exciting opportunity to unite our vibrant community and celebrate our shared achievements.

In 2023, we achieved significant milestones. The Biopharma 2.0 Annual Conference attracted 500 attendees, offering five diverse tracks on scientific research, business strategies, clinical development & regulations, data science, and career development. Building on this success, the @Philly Cell and Gene Therapy Conference was a resounding hit, garnering over 500 attendees and substantial media coverage. This event solidified our region's leadership in CGT innovation, fostering valuable connections and collaborations across industry sectors.

Dedicated to member development, we delivered career and scientific webinars, while our collaboration with ISWT on the Bioverse webinar series, featuring esteemed experts, further enriched our members' pharmaceutical business knowledge. On the social front, our successful fall picnic for volunteers and Lunar New Year dinner party strengthened bonds within our community. We remain deeply grateful to our sponsors and volunteers, whose unwavering support was essential. Additionally, we proudly support the DVSF by offering student scholarships to foster STEM education for the next generation.

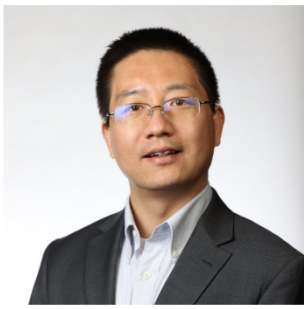
This year's Annual Conference, "Innovating Biopharma Frontier: A Path to Growth and Impact," delves into the evolving pharmaceutical landscape, showcasing cutting-edge advancements in drug discovery, digital technologies/AI, and innovative business models navigating the current market**.** This event promises invaluable insights for all industry stakeholders, potentially igniting investment opportunities, M&A activity, and global partnerships.

We extend our heartfelt appreciation to our dedicated leadership, functional teams, and exceptional volunteers. Your tireless efforts and dedication to our mission and vision propel us forward. We also acknowledge and thank our advisors, sponsors, collaborators, speakers, and attendees of our past events. Your contributions are instrumental in furthering our organization's goals.Thank you again for joining us at the 2024 Annual Conference. We trust you will find it informative, inspiring, and enjoyable. Your participation embodies our collective commitment to making a positive impact on industry and beyond.

Sincerely,

SAPA-GP President Office

Yang Yuan(President 23-24)



Yufeng Li (President elect 24-25)

Haichen Yang (Immediate Past President 22-23)

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SAPA-GP Annual Conference Day 1

P.M.	**Workshop:** Leveraging Generative AI to Work Smarter, Not Harder

Executive Summit (By Invitation Only)

SAPA-GP Annual Conference Day 2

A.M.	**Drug Discovery and Development** Session 1: Novel Targets and Modalities Selection in Drug Discovery	**Enabling Technology to Accelerate Clinical Development** Session 1: Frontiers in Regulatory Science

Company Sponsored Lunch Sessions

P.M.	**Drug Discovery and Development** Session 2: Efficacy and Safety Assessment from Preclinical Models to Clinical Studies Session 3: AntibodyPlus: The Emerging Trend of Antibody Based Therapeutics *(In collaboration with the Chinese Antibody Society)*	**Enabling Technology to Accelerate Clinical Development** Session 2: Application of Novel Methodologies in Drug Development & Approval Session 3: Technologies for Clinical Development

CLOSING REMARKS

RECEPTION

MAR 8th, 2024

Workshop:

Leveraging Generative AI to Work Smarter, Not Harder

Executive Summit (By Invitation Only)

March 9th, 2024, KEYNOTE SPEECH

AI & Data Science	Thriving in Challenging Environment	Innovations in BioCMC
Session 1: Foundations and Methodologies of AI	Session 1: In Asia for Global	Turbocharging Innovation in Biologic Drug Product and Manufacturing

Company Sponsored Lunch Sessions

AI & Data Science	Thriving in Challenging Environment	Career Development
Session 2: Transformative Applications of AI in the Pharmaceutical Industry Session 3: Demystifying Real-World Data in Pharmaceutical Innovation	Session 2: Negotiating a Better Term Sheet Session 3: Institution, Government, and Location Business Ecosystem	• Non-clinical Safety Assessment • Clinical Pharmacology & Translational Medicine • Regulatory Affairs • CMC & Quality • Clinical and Medical Affairs • Health Economics and Outcome Research

CLOSING REMARKS

RECEPTION

AGENDA Friday, March 8th, 2:00 p.m.-8:00 p.m.

Plenary Session — Centennial Ballroom 1

2:00-5:00 p.m.	**Workshop: Leveraging Generative AI to Work Smarter, not Harder** Lixia Yao, Ph.D., President & CEO, Polygon Health Analytics Fang Shen, Ph.D., VP of Target Biology, Immunome
6:00-8:00 p.m.	**Executive Summit and Leadership Award Presentation** (By Invitation Only) Room: Wayne & Villanova

AGENDA Saturday, March 9th, 8:45 a.m.-6:15 p.m.

Plenary Session — Grand Ballroom

8:45-9:00 a.m.	**Opening Remark & Welcome, President-elect Announcement & Speech**
Session chair:	Yang Yuan, Ph.D., President, SAPA-GP; Associate Director, Jazz Pharmaceuticals Yufeng Li, Ph.D., President Elect SAPA-GP
	Keynote Speech:
9:00-9:45 a.m.	**Path towards Value Creation - China Biopharma Innovation Trends** Fangning Zhang, M.B.A., Partner, McKinsey & Company
9:45-10:30 a.m.	**Generative AI for Healthcare and Life Science** Hua Xu, Ph.D., Robert T. McCluskey Professor, Vice Chair for Research and Development at Section of Biomedical Informatics and Data Science, Assistant Dean for Biomedical Informatics at Yale School of Medicine, Yale University
10:30-10:50 a.m.	**Coffee Break**

10:50-12:10 p.m. Parallel Sessions

Scientific Track: Advances in Discovery and Development of Evolving Biotherapeutics — Centennial Ballroom 3

Session 1: Novel Targets and Modalities Selection in Drug Discovery

Session chair:	Yu Chen, Ph.D., Senior Director, Lilly Research Lab, Eli Lilly and Company
10:50-11:20 a.m.	**RNA Lipid Nanoparticles: Engineering Improved Safety and Efficacy** Jacob Brenner, M.D., Assistant Professor of Departments of Medicine and Pharmacology, University of Pennsylvania
11:20-11:50 a.m.	**Modality-Enabled Drug Discovery: An Oral Cyclic Peptide for PCSK9** Robert Garbaccio, Ph.D., VP, Head of Discovery Chemistry, Merck & Co
11:50-12:10 p.m.	**Emerging Opportunities to Harness Large Scale Multi-modal Data for Evolving Horizons in Drug Discovery: An Introduction to Data Sources and Applications** Yu Chen, Ph.D., Senior Director, Lilly Research Lab, Eli Lilly and Company

Clinical Track: Enabling Technology to Accelerate Clinical Development — Grand Ballroom

Session 1: Frontiers in Regulatory Science

Session chair(s): Long Wang, M.D., Ph.D., Vice President, Head of Vaccine Development, Takeda

10:50-11:20 a.m. **China's Drug Development Overseas: Regulatory, Clinical Trials and Commercial Closure**
Leon Liying Sun, Ph.D., M.D., Chief Medical Officer, Feirui Biopharmaceutical Corp

11:20-11:50 a.m. **Pushing the Boundaries: Using Artificial Intelligence in Drug Development in a Regulated Environment**
Heidi Wang, Ph.D., CEO, OBI Pharma

11:50-12:10 p.m. **Drug Development Opportunities and Challenges - Regulatory Perspective**
Liman Wang, Ph.D., Director of Global Regulatory Affairs, Merck & Co

Business Development: Thriving in a Challenging Business Environment
Centennial Ballroom 2

Session 1: In Asia for Global

Session chair: Leon Tang, Ph.D., M.S., Founding Partner, InScienceWeTrust Advisory & ISWT-Community

10:50-12:10 p.m. **Panel Discussion**

Weiyong Sun, Ph.D., M.D., M.B.A., CBO, Hansoh Pharma
Nikolaos George, Ph.D., J.D., Partner, Life Sciences Intellectual Property, Jones Day
Bing Yuan, Ph.D., M.B.A, Co-founder, Chairman & CEO, OnCusp Therapeutics
Aaron Feng Chen, Ph.D., CBO, Accutar Biotechnology

Data & AI: The AI & Data Sciences Frontier to Elevating Pharmaceutical Innovation
Frazer

Session 1: Foundations and Methodologies of AI

Session chair: Lixia Yao, Ph.D., President and CEO, Polygon Health Analytics LLC

10:50-11:20 a.m. **Real World Challenges of Clinical AI**
Fei Wang, Ph.D., Professor of Population Health Sciences, Cornell University

11:20-11:50 a.m. **From Chaos to Clarity: Identifying Structures and Meaning from Text**
Weimao Ke, Ph.D., Associate Professor & Associate Department Head, Information Science, Drexel University

11:50-12:10 p.m. **Exploring the Impact and Real-World Applications of AI in Healthcare**
Ying Li, Ph.D., Director of HEOR, Regeneron Pharmaceuticals, Inc.

CMC: Turbocharging Innovation in Biologics Drug Product and Manufacturing
Centennial Ballroom 1

Session chair: Haichen Nie, Ph.D., Associate Director, Teva Pharmaceuticals

10:50-11:20 a.m. **Building a Framework for Technology Transfer for Late-Phase and Commercial Production**
Shawn Allwein, Ph.D., VP Biologics CMC, Specialty Research & Development, Teva

11:20-11:50 a.m. **Turbocharging Innovations in Biologics Drug Product Development and Manufacturing**
Sujatha Sonti, Ph.D., VP, Drug Product Development, Sr. Scientific Fellow, GSK

11:50-12:10 p.m. **Challenges and Opportunities in the Biopharmaceutical Formulation Development**
Frank Li, Ph.D., Executive Director, Wuxi Biologics

12:10-1:30 p.m. **Lunch Break and Networking**

12:20-1:20 p.m. **Lunchtime Session**

Conversation with GenScript **Room: Malvern**

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

Robust Production of Antibody Fragments and Their Therapeutic Applications
Aria Zhang, Ph.D., BD Executive II, GenScript USA Inc.

Conversation with WuXi AppTec **Room: Haverford**

Session chair: Zhiyi Cui, Ph.D., Associate Director, DMPK Modeling, GSK

Unveiling WuXi AppTec's Innovative Approaches in the Identification of Covalent Small Molecule Binders
Zhifeng Yu, Ph.D., Director of Assay & DEL Screen, WuXi AppTec

Conversation with Goby Global LLC **Room: Paoli**

Session chair: Hui Wang, Ph.D., Head of US Business Development, Genevoyager

Breaking Barriers: Enhancing Partnering Opportunity and Value for Chinese Biotech Companies through Strategic PR Initiatives
Bob Ai, Ph.D., M.B.A., Founder and Managing Partner, Goby Global LLC

1:30-2:30 p.m. Parallel Sessions

Scientific Track: Advances in Discovery and Development of Evolving Biotherapeutics
Centennial Ballroom 3

Session 2: Efficacy and Safety Assessment from Preclinical Models to Clinical

Session chair: Tong-Yuan Yang, Ph.D., Senior Scientific Director, Preclinical Sciences and Translational Safety, Johnson & Johnson

1:30-2:00 p.m. **Immunogenicity Assessment of mAb Therapeutics and its Clinical Relevance**
Tong-Yuan Yang, Ph.D., Senior Scientific Director, Preclinical Sciences and Translational Safety, Johnson & Johnson

2:00-2:30 p.m. **Nonclinical Drug Safety: Innovating Across Scientific, Regulatory & Operational Considerations**
Rupesh Amin, Ph.D., Executive Director, Nonclinical Drug Safety, Merck & Co

2:30-3:00 p.m. **Starting Dose Selection in Consideration of Safety and Efficacy in First in Human Study**
Alex Qiu, Ph.D., M.D., Executive Director, TA Lead for Oncology Solid Tumor Early Assets, External Relationship, BMS

Clinical Track: Enabling Technology to Accelerate Clinical Development Grand Ballroom

Session 2: Application of Novel Methodologies in Drug Development & Approval

Session chair:	Yali Liang, M.D., Global Clinical Pharmacology & Pharmacometrics, Jazz pharmaceuticals
1:30-2:00 p.m.	**AI-Powered Regulatory Intelligence** Joga Gobburu, Ph.D., Professor of Center for Translational Medicine, University of Maryland
2:00-2:30 p.m.	**Model-Informed Approaches to Enhance Drug Development and Patient Care - Present & Future** Jiang Liu, Ph.D., Associate Director for Therapeutic Review, FDA
2:30-3:00 p.m.	**Mechanistic Modeling and Virtual Patients in Clinical Drug Development** Anna Kondic, Ph.D., M.B.A., M.A., B.S., Head of Pharmacometrics, BMS

Business Development: Thriving in a Challenging Business Environment Centennial Ballroom 2

Session 2: Negotiating a Better Term Sheet

Session chair:	Cynthia Cai, Ph.D., Venture Partner, Viva BioInnovator
1:30-3:00 p.m.	**Panel Discussion** Michele Washko, M.B.A., M.A., B.A., CEO, Life Sciences Greenhouse Investments Robert Dickey, M.B.A., Managing Director, Foresite Advisors Enna Weng, M.B.A., Managing Director, Freedom Capital Markets Zhen Yang, Ph.D., Director of Global Business Development & Alliance management, Hansoh Pharma

Data & AI: The AI & Data Sciences Frontier to Elevating Pharmaceutical Innovation Frazer

Session 2: Transformative Applications of AI in the Pharmaceutical Industry

Session chair:	Xiang (Mike) Yu, Ph.D., Director Analytics and Insights, Johnson & Johnson
1:30-2:00 p.m.	**RWE and AI: a Lethal Combination?** John Cai, Ph.D., M.D., Executive Director, Merck & Co.
2:00-3:00 p.m.	**Panel Discussion: AI Frontiers in Healthcare: Revolutionizing Medicine with Generative Intelligence** Ganhui Lan, Ph.D., VP, Head of Data Science and Machine Learning, Pfizer Andrew Chanlam, Pharm.D., M.B.A., Senior Director, Johnson & Johnson John Cai, Ph.D., M.D., Executive Director, Merck & Co. Weimao Ke, Ph.D., Associate Professor & Associate Department Head, Information Science, Drexel University
3:00-3:20 p.m.	**Coffee Break**

3:20-4:50 p.m. Parallel Sessions

Scientific Track: Advances in Discovery and Development of Evolving Biotherapeutics Centennial Ballroom 3

Session 3: AntibodyPlus: the Emerging Trend of Antibody based Therapeutics
(in collaboration with the Chinese Antibody Society)

Session chair:	Kai Wang, Ph.D., Senior Scientist, Cell Culture and Fermentation Sciences, Merck & Co
3:20-3:50 p.m.	**AntibodyPlus: the Future Trend of Antibody-based Therapeutics** Shawn Shouye Wang, Ph.D., Founder and Board Director, Chinese Antibody Society; Senior Director, WuXi XDC
3:50-4:20 p.m.	**Antibody-drug Conjugates for Oncology** Victor Goldmacher, Ph.D., CSO, ImmuVia, Inc.
4:20-4:50 p.m.	**Advancements in BsAbs and TCEs: Navigating the Post-ADC Era** Han Li, Ph.D., CEO, NovaRock Biotherapeutics Ltd

Clinical Track: Enabling Technology to Accelerate Clinical Development **Grand Ballroom**

Session 3: Technologies for Clinical Development

Session chair:	Dongjing Fu, M.D., Ph.D., Senior Director of Neuroscience, Johnson & Johnson
3:20-3:50 p.m.	**Quantitative Drug Development** Mat Davis, Ph.D., VP of Data Science, Jazz Pharmaceuticals
3:50-4:20 p.m.	**Using Data Science and Site Intelligence Hub to Accelerate Feasibility, Site Selection & Study Start-Up** Asha Mahesh, M.S., Sr. Director R&D Data Science and Digital Health, Johnson & Johnson
4:20-4:50 p.m.	**How Predictive and Generative AI can accelerate clinical development** Dave Latshaw II, Ph.D., M.B.A., CEO & Co- Founder, BioPhy

Data & AI: The AI & Data Sciences Frontier to Elevating Pharmaceutical Innovation Frazer

Session 3: Demystifying Real-World Data in Pharmaceutical Innovation

Session chair:	Wei Zhou, Ph.D., M.D., Associate Vice President of Value, Evidence, and Outcomes, Eli Lilly and Company
3:20-3:50 p.m.	**Overview of Real-World Evidence Regulatory Policy** Haijun Tian, Ph.D., Associate Vice President of Value, Real World Evidence Strategy, Eli Lilly and Company
3:50-4:20 p.m.	**Real-World Data (RWD) in Precision Oncology: Facilitating Clinical Development** Changxia Shao, Ph.D., M.P.H., Senior Director of Pharmacoepidemiology, Merck & Co.
4:20-4:50 p.m.	**Real-world Evidence Generation in Support of Product Launch and Scientific Differentiation** Jinghua He, Ph.D., M.P.H., Group Director of Real-World Value & Evidence, Johnson & Johnson

Business Development: Thriving in a Challenging Business Environment
Centennial Ballroom 2

Session 3: **The Institution, Government, and Local Business Ecosystem**

Session chair:	Bryan Tsao, Ph.D., Manager of Life Sciences, Chamber of Commerce for Greater Philadelphia
3:20-4:50 p.m **.**	**Panel Discussion:** Rebecca L Grant, DVM, Director, Life Sciences & Biotechnology for the Commerce Department, The city of Philadelphia Yi-Yen Chen, Ph.D., Associate Director, PCI Ventures, UPenn Matthew Cabrey, B.A., Director, Ideas x Innovation Network (i2n) of Chester County Economic Development Council Thomas Kim, J.D., M.S., CEO, EpiVario Inc.

Career Track: Building Your Career Blueprint: Insights into Drug Development Functions
Centennial Ballroom 1

Track chairs:	Evelyn Guo, M.D., M.B.A., M.S., Medical Director, Genmab Zak Huang, M.D., Vice President of US Regulatory Affairs, Hansa Biopharma
3:20-4:50 p.m.	**Non-clinical Safety Assessment** Yun Zhang, Ph.D., Drug Safety Team Lead (DSTL) of Drug Safety R&D (DSRD), Pfizer **Clinical Pharmacology and Translational Medicine** Jennifer Sheng, Ph.D., VP, Clinical Pharmacology and Pharmacometrics, Incyte **Regulatory Affairs: My Entrepreneurship Journey in Regulatory Affairs** Andrew Jiang, M.B.A., M.S., President, Aleon Pharm International **CMC and Quality** Haichen Nie, Ph.D., Associate Director, Teva Pharmaceuticals Zhicheng Xiao, Ph.D., Director of CMC, GSK **Clinical and Medical Affairs: Clinical development 101, What Who and How** Evelyn Guo, M.D., M.B.A., M.S., Medical Director, Genmab Sue Hellie, M.D., M.B.A., Head, General Medicine, Global Medical Affairs, Regeneron Pharmaceuticals **Health Economics and Outcome Research** Ying Li, Ph.D., Director of HEOR, Regeneron Pharmaceuticals Boshu Ru, Ph.D., Director, Real-world Data Analytics and Innovation, Merck & Co.
5:30-6:15 p.m.	**Roundtable Discussion**
5:00-5:30 p.m.	**Closing Remarks: Yufeng Li, Ph.D.** **Raffle Drawing: Xinjun Zhang, Ph.D.**
5:30-6:15 p.m.	**Reception**

SAPA-GP Leadership

Yang Yuan, President (2023-2024)
Yufeng Li, President-Elect (2024-2025)
Haichen Yang, Immediate past President (2022-2023)

Annual Conference Leadership Team

Xinjun Zhang
Evelyn Guo

Program Track and Session Lead

Cynthia Cai
Evelyn Guo
Haichen Nie
Hui Wang
Lixia Yao
Yu Chen
Zak Huang
Fang Shen
Kai Wang
Xiang Yu
Jake Dong
Yali Liang
Leon Tang
Long Wang
Wei Zhou
Dongjing Fu
Bill Lu
Bryan Tsao
Tong-Yuan Yang

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He Dian
Di Wu
Yifan Gong
Saisi Xue
Hui Wang
Ronghui Zhou
Sherry Wang

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Zhiyi Cui
Derek Huang
Wenji Lei
Kaixuan Liu
Jessica Mo
Yulanda Tang
Mindy Wang
Sarah Weng
Nancy Yu
Emily Zou

KEYNOTE SPEAKERS

Hua Xu, Ph.D.

Robert T. McCluskey Professor, Vice Chair for Research and Development at Section of Biomedical Informatics and Data Science, Assistant Dean for Biomedical Informatics at Yale School of Medicine
Yale University

Dr. Hua Xu is a Professor and the Vice Chair for Research and Development in the Section of Biomedical Informatics and Data Science at Yale School of Medicine (YSM), where he also serves as Assistant Dean for Informatics. He earned his Ph.D. in Biomedical Informatics from Columbia University. His primary research interests include biomedical natural language processing (NLP) and data mining, as well as their applications in secondary use of electronic health records data for clinical and translational research. Dr. Xu's research is funded by multiple agencies including NLM, NCI, NIGMS, NIA, AHA, and CPRIT. The methods and tools developed in his lab have been top-ranked in a number of biomedical NLP shared tasks and widely used to support diverse biomedical applications. He previously served as the Chair of American Medical Informatics Association (AMIA) NLP Working Group and currently leads the Observational Health Data Sciences and Informatics (OHDSI) NLP Working Group. Dr. Xu is a fellow of the American College of Medical Informatics, elected in 2014.

Fangning Zhang, M.B.A.

Partner
McKinsey Company

Fangning is the Partner of Greater China Life Sciences practice in McKinsey, she has served leading multi-national pharma companies and China innovators on a broad range of topics including corporate strategy, R&D/innovation, digital transformation, Business Development, and organization transformation etc. Fangning leads services to biopharma innovators in China. She's led the efforts to host regular executive roundtables, built a service community internally, and continuously engaged industry leaders to shape forward looking perspective Fangning is a regular speaker at leading China healthcare conferences, e.g., China Trials (2015-20), China Healthcare Investment Conference (2016, 2018), Biocentury China Healthcare Summit (2018, 2020). She's spearheaded efforts to establish China Drug Innovation Index (CDII) since 2015 and published series of reports and articles on China biopharma innovation (e.g., "Vision 2028 -How China could impact the global biopharma industry"). Prior to McKinsey, Fangning has worked as research scientist for 6 years at Pfizer Global R&D center (Groton, CT), conducting drug discovery research as medicinal chemist in Anti-infectives, Immunology and Oncology

SPEAKERS

Bob Ai, Ph.D., M.B.A.

Founder and Managing Partner
Goby Global LLC

Bob Ai, Ph.D. MBA, is the founder and Managing Partner of Goby Global, which provides financial communications (IR and PR), cross-border licensing, fundraising, and other strategic advisory services. Goby also publishes a newsletter covering healthcare news in Asia-Pacific region. Bob was previously a Managing Director at Solebury Trout, a subsidiary of PNC Bank. Prior to Solebury Trout, he held roles as a hedge fund analyst, private equity fund principal, senior sell-side analyst, and public company chief financial officer. Bob also serves as Chief Financial Officer (CFO) of EDOC Acquisition Corp. Bob received his PhD and MBA from Penn State University and completed postdoctoral training at University of Pennsylvania. He has published several articles in peer-reviewed scientific journals and was awarded the prestigious Ray Wu (CUSBEA) scholarship for outstanding Chinese student to study abroad. Bob holds Series 7, 63, 79, 86, and 87 securities licenses, which are currently inactive.

Shawn P. Allwein, Ph.D.

Vice President of Biologics CMC
Teva Pharmaceuticals

Shawn earned his PhD from the University of Arizona in Synthetic Organic Chemistry which was followed by an NIH Postdoctoral Fellowship at the University of North Carolina, Chapel Hill. His initial entry into the pharmaceutical industry was within Merck's small molecule Process Research group before moving to Cephalon and then Teva Pharmaceuticals. Prior to shifting to biologics, Shawn oversaw Teva's small molecule process development group and internal pilot plant manufacturing of clinical supplies. During this time, he generated over 30 publications in peer reviewed journals. As part of Teva's focus on biologics, Shawn shifted to large molecule R&D within CMC, with a focus on clinical manufacturing. Initially overseeing continuous improvement efforts in manufacturing, Shawn's role expanded to oversee Teva's Biologics Manufacturing Facility for Teva's novel biologics and biosimiliar clinical programs. In 2021, Shawn became the Vice President of Biologics CMC overseeing Drug Substance, Drug Product and Analytical Development along with Manufacturing and Operations.

Rupesh P Amin, Ph.D.

Executive Director, Nonclinical Drug Safety
Merck & Co

Dr. Rupesh P. Amin is an Executive Director in Nonclinical Drug Safety at Merck. He has 22 years of experience from both small and large pharmaceutical companies across various aspects of toxicology, investigative toxicology, nonclinical drug discovery and development across multiple therapeutic areas and modalities. Rup has successfully supported the advancement of Cardiometabolic, Anti-inflammatory, Oncology and RNA therapeutic drugs. In his current role as Head of Program Development, Dr. Amin provides nonclinical drug safety scientific, operational, and strategic oversight for Merck's development programs across all therapeutic areas and modalities. His team supports programs from Phase 1 through registration and post-marketing, ensuring nonclinical drug safety aspects are appropriately addressed. Additionally, Dr. Amin's team provides oversight of Occupational Toxicology aspects of Merck's portfolio. This involves critically assessing the potential hazardous effects of chemicals and drugs to guide the implementation of measures to protect employee health and safety. Before joining industry in 2002, Dr. Amin completed a Ph.D. in Toxicology at the Joint Graduate Program in Toxicology at Rutgers University/Robert Wood Johnson Medical School. He further pursued a post-doctoral fellowship applying toxicogenomic approaches to elucidate molecular mechanisms in drug-induced renal toxicity and studied cell cycle defects at the National Institute of Environmental Health Sciences. Rup enjoys travelling, hiking and exploring diverse cuisines with his wife and 3 kids.

Jacob Brenner, M.D.

Assistant Professor of Departments of Medicine and Pharmacology
University of Pennsylvania

Dr. Jake Brenner, MD, PhD is an assistant professor & attending physician in the University of Pennsylvania's (U

Penn) Departments of Medicine and Pharmacology. He joined the U Penn faculty in 2018, where he spends 6 weeks each year taking care of patients in the ICU, and the rest developing drug delivery technologies for the critical illnesses he treats in the ICU. His lab primarily delivers siRNA and mRNA via targeted lipid nanoparticles (LNPs), engineering these LNPs as therapeutics to test in multiple animal models of stroke, ARDS, and sepsis, and in ex vivo human organs. The lab has also identified multiple innate immune mechanisms activated by LNPs, and then used computational modeling and engineering to build safer, more effective LNPs. The lab is funded by government grants and by several companies, and has spun out multiple medical technology companies. For more info, see `www.brennerbioengineeringlab.com`.

Matthew Cabrey, B.A.

Director
Ideas x Innovation Network (i2n) of Chester County Economic Development Council

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 consistent of corporate, university, civic and community organizations; and our i2n Entrepreneurs, which consist of early-stage and well-established creators and innovators.

With more than 30 years of experience in the economic development, biopharmaceuticals, financial services, marketing and communications, media, and nonprofit sectors, Matt is also an entrepreneur, having founded Growing Greater LLC, a strategic business and communications advisory firm. 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.

Cynthia Cai, Ph.D.

Venture Partner
Viva BioInnovator

Dr. Cynthia Cai is an executive and investor with over twenty-five years of experience in the healthcare and life science industry. Extensive experience in equity investment, board membership, marketing, and business development. In-depth understanding of global biotech and life science business, widely recognized as having a unique ability to bridge collaboration between scientists and businesses, between the Eastern and Western worlds. Dr. Cai is the founder and president of Tharton Consulting, which provides investment and management consulting services. She is also a venture partner of Viva BioInnovator, an equity investor in biotech innovation with novel solutions to cross multiple therapeutic areas. Before that, she served as senior advisor to Northern Light Venture Capital, for its healthcare investment effort in the United States. Previously Dr. Cai had progressive leadership roles with Agilent Technologies, as global associate vice president of marketing, she was responsible for its billion-dollar Chromatography, Automation, and Mass Spec. business. Dr. Cai serves on the board of directors for Spectral AI (NASDAQ: MDAI), Arthrosi Therapeutics, AceLink Therapeutics, Amberstone Biosciences, and Basking Biosciences. She is also a member of the board of the Science History Institute in Philadelphia. Dr. Cai earned a B.A. and M. Eng. from Tsinghua University in Beijing, received her Ph.D. in Chemistry from the University of Massachusetts, and an MBA from The Wharton Business School of the University of Pennsylvania. She had been a regular speaker at healthcare investment conferences such as BIO International Convention; RESI; China Focus at J.P. Morgan, SAPA Annual Conference, and Wharton China Business Forum. Dr. Cai is also a long-time career advisor for Tsinghua Global MBA and Wharton Executive MBA students.

John Cai, M.D., Ph.D.

Executive Director
Merck

John Cai, M.D., Ph.D., FAMIA, is Executive Director, Real world Data Analytics and Innovation, in the Merck Center for Observational and Real-World Evidence (CORE). He is leading a team of data scientists and outcomes researchers to generate real-world evidence and in-

sights through innovative and advanced analytics. John has more than 20 years of experience in biomedical and clinical research across academic, biotech, and pharmaceutical settings. John received his medical training from China Medical University and his Medical Informatics training from Harvard Medical School. Pursuing a passion for both medicine and computing, John has co-authored peer reviewed publications in the areas of medical informatics, machine learning, clinical trials, and cancer genomics. John is a Fellow of the American Medical Informatics Association (AMIA) and serves in the AMIA Industry Advisory Council.

Aaron Feng Chen, Ph.D.

CBO
Accutar Bio

Dr. Aaron Feng Chen is currently CBO at Accutar Bio. Aaron brings over 15 years of experience in consulting, biotech, and pharma. Aaron has held increasing responsibilities in a variety of research, strategy, and commercial roles (including strategic planning, market access, marketing, and sales operation). He joined Accutar Biotech from Bayer (2010–2020), where he worked most recently as Senior Director of Global Business Development and Licensing, leading early licensing efforts in oncology. He was part of the Bayer teams establishing and/or executing the Loxo partnership on Vitrakvi® (larotrectinib), the Janssen partnership on Xarelto® (rivaroxaban), and other important licensing and clinical collaboration deals. He also worked as a strategy consultant at McKinsey Company (2008–2010), and a research analyst at Beijing Genomics Institute (2001–2003). Aaron obtained his Master of Science degree in biochemistry and Doctorate degree in computational biology from the University of Pennsylvania. He has published over 10 articles in top peer-reviewed journals, including Science and Nature Reviews Drug Discovery, with over 3000 citations.

Andrew Chanlam, Pharm.D., M.B.A.

Senior Director
Johnson & Johnson Innovative Medicine

Andrew Chanlam is the Senior Director, Digital Medical Innovation, Scientific Affairs at Johnson & Johnson Innovative Medicine. He has over 29 years of medical, business and digital excellence leadership experience in various scientific and medical affairs functions. In his current role, Andrew is responsible for driving digital transformation and innovation strategy development and execution to transform scientific customer engagement. During his tenure at Johnson & Johnson, Andrew has provided strategic and operational leadership in a broad variety of scientific and medical functions such as Medical Information, Field Scientists Operations, Medical Call Center Operations, Advanced Analytics & AI, Medical/Scientific Intelligence, Knowledge Management, Digital Customer Engagement, Strategic Portfolio Management, Learning & Professional Development, Compliance & Auditing and Safety Operations

Andrew has a Bachelor of Science degree in Biochemistry, a Doctor of Pharmacy degree in addition to his MBA in Pharmaceutical Management. He completed his postdoctoral residency in Drug Information

Yi-Yen Chen, Ph.D.

Associate Director
PCI Ventures UPenn

Dr. Yi-Yen Chen has over 10 years of healthcare-related experience. Prior to joining PCI Ventures, she oversaw the life sciences investment and portfolio management at Echo Investment Capital. She also worked in business development and drug licensing at Microbio Group in Taiwan. Dr. Chen was the R&D project head and led the development of the world's biggest antibody portfolio for the zebrafish research community at GeneTex.

She completed her PhD in developmental biology from Nobel Laureate Professor Christiane Nüsslein-Volhard's lab at the Max-Planck Institute in Germany. Her postdoctoral training was in molecular biology at the Institute of Molecular Biology in Mainz, Germany, and in cancer immunotherapy at the Netherlands Cancer Institute in Amsterdam.

Yu Chen, Ph.D., P.M.P.

Senior Director, Lilly Research Laboratories
Eli Lilly and Company

Yu Chen is the Senior Director at Lilly Research Laboratories, Eli Lilly and Company. He initiates and executes translational science strategy in the Diabetes, Obesity, and Complications research organization. Before joining Lilly, he worked at Pfizer, Monsanto, and Novartis companies.

Yu received his Ph.D. in Bioinformatics from the University of Tennessee-Oak Ridge National Laboratory Graduate School of Genome Science and Technology.

Mat Davis, Ph.D.

VP of Data Science
Jazz Pharmaceuticals

Mat Davis serves as the Vice President of Data Science at Jazz Pharmaceuticals, a global biopharmaceutical company. He oversees a team of 120 employees across all aspects of drug development including pharmacoepidemiology, clinical biostatistics, medical affairs statistics, bioinformatics, real world evidence, and integrated data analytics and statistical programming. Prior to Jazz, Mat was at Teva Pharmaceuticals, providing statistical and biometrics leadership. Throughout his decade long career, Mat participated in multiple product review committees where he has provided insights on integrated product development plans and leveraged statistical probability to assess the technical and regulatory success of target product profiles and championed the use of complex, innovative clinical trial designs alongside quantitative decision-making metrics for clinical go/no-go criteria. He is a quantitative leader with a passion for ensuring that data scientists play a key role in the drug development lifecycle to provide innovative, best in class experimental design and interpretation to accurately and efficiently make safe and effective medicines available to patients in need.

Robert Dickey, M.B.A.

Managing Director
Foresite Advisors

Robert Dickey IV has over 25 years' experience as a CFO as well as in other C-level and Board positions in both private and publicly-traded life sciences and medical device companies. Mr. Dickey is experienced in all stages of the corporate lifecycle, including start-up, fundraising, going public, high growth, turnarounds and exit strategies. Earlier in his career, Mr. Dickey spent 18 years in investment banking, mostly at Lehman Brothers, with a background split between M&A and capital markets transactions. His expertise includes public and private financings, M&A, partnering/licensing transactions, project management, overseeing company's finance and accounting functions, as well as interactions with Boards, VCs, shareholders and Wall Street. He is currently a Managing Director at Foresite Advisors which provides finance support and strategy for life science companies, including strategic CFO advisory, financial analysis and transactional support for fundraising and M&A. Mr. Dickey is also part of the Leadership Team at Cell One Partners, which provides consulting for cell and gene therapy companies. He currently serves as a member of the Board of Directors at AngioGenex, SFA Therapeutics and GSNO Therapeutics. Mr. Dickey holds an MBA from The Wharton School, University of Pennsylvania, and an AB from Princeton University.

Robert Garbaccio, Ph.D.

Vice President, Head of Discovery Chemistry
Merck

Dr. Rob Garbaccio received his B.A. in chemistry from Boston University, his Ph.D. from The Scripps Research Institute and was a NIH postdoctoral fellow at Memorial Sloan Kettering Cancer Center. Rob joined Merck Discovery Chemistry, West Point, in 2001 where he contributed to and led small molecule programs spanning oncology, neuroscience and infectious disease. Subsequently, Rob took a leap into a leading polymer- and antibody-mediated delivery of siRNA programs. Rob also served as chemistry lead for the Merck-Ambrx collaboration for the development of antibody drug conjugates beyond oncology as well as the Merck-Peptidream collaboration for the application of macrocyclic peptides to challenging targets. Since 2016, Rob has taken positions of increasing scope helping Merck Research Labs to become modality-enabled with a focus on cyclic peptides. In late October 2020, Rob was named Vice President, Head of Discovery Chemistry and has the privilege of working with an incredible team.

Nikolaos (Nick) George, Ph.D., J.D.

Partner, Life Sciences Intellectual Property
Jones Day

Nick George has more than 30 years of experience developing and evaluating biologics-based patent portfolios. He has devised worldwide patent strategies involving such diverse technologies as therapeutic antibodies, antibody drug conjugates, cellular therapeutics (including stem cell, natural killer cell, macrophage, regulatory cell, chimeric antigen receptor, and induced pluripotent stem cell [iPSC] therapeutics), gene therapies, oncolytic viruses, gene edit-

ing, mRNA therapeutics, peptide therapeutics, diagnostics, and enzyme replacements, among others.

Joga Gobburu, Ph.D., M.B.A.

Professor of Center for Translational Medicine
University of Maryland, Baltimore

Dr. Gobburu is a Professor with the School of Pharmacy and the School of Medicine, University of Maryland, Baltimore, MD, USA. He held various positions at the US FDA between 1999 and 2011. Under his leadership, a Division of Pharmacometrics was formed at the FDA and several policies were established. He is a world-recognized scientific leader in the area of quantitative disease models and their application to decisions. Dr. Gobburu is best known for transforming the field of Pharmacometrics across the world into a decision-supporting science. He also established a Pharmacometrics Fellowship program at the FDA. He received numerous FDA awards such as the Outstanding Achievement Award. He also received the Outstanding Leadership Award from the American Conference on Pharmacometrics (2008), the Tanabe's Young Investigator Award from the American College of Clinical Pharmacology (ACCP) (2008) and the Sheiner-Beal Pharmacometrics Award from the American Society of Clinical Pharmacology and Therapeutics in 2019. Dr. Gobburu is on the Editorial Boards of several journals and a Fellow of ACCP, AAPS and International Society of Pharmacometrics. He has published over 120 papers and book chapters. He is co-founder of PumasAI Inc., and Vivpro Corporation.

Victor Goldmacher, Ph.D.

CSO
ImmuVia, Inc.

Education: Moscow State University, Moscow, USSR BS/MS 06/1974 Physical chemistry/enzymology Moscow State University, Moscow, USSR PhD 09/1977 Enzymology/biochemistry Massachusetts Institute of Technology, Postdoctoral Training N/A 09/1983 Cell Biology/Toxicology

Positions 1977 – 1979 Research Scientist, National Cardiology Research Center, Moscow, USSR 1981 - 1983 Postdoctoral Associate, Department of Applied Biological Sciences, Massachusetts Institute of Technology, Cambridge, MA 1983 – 1986 Associate in Pathology, Dana-Farber Cancer Institute and Harvard Medical School 1986 - 1988 Assistant Professor of Pathology, Dana-Farber Cancer Institute and Harvard Medical School 1988 - 1994 Director of Immunobiology, ImmunoGen, Inc., Cambridge, MA 1994 - 1999 Cytomegalovirus Project Leader, Apoptosis Technology, Inc., a subsidiary of ImmunoGen, Inc. 2000 - 2006 Director, Head of the Department of Cell Biology, ImmunoGen, Inc., Cambridge, MA 2006 – 2016 Senior Director, Head of the Department of Cell Biology, ImmunoGen, Inc., Waltham, MA 2016 – 2020 Director of Discovery, Forbius, Inc., Montreal, Quebec, Canada 2017 – current Chief Scientific Officer, ImmuVia, LLC, Cambridge, MA

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Patents: `https://www.ncbi.nlm.nih.gov/sites/myncbi/1PK-Qjl5tc9Ql/bibliography/52293682/public/?sort=date\&direction=ascending`.

Rebecca L Grant, DVM (Doctor of Veterinary Medicine)

Director, Life Sciences & Biotechnology for the Commerce Department
The 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 decided to accept 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 and then Cambridge Innovation Centers (CIC) before accepting a position as Director of Life Sciences and Biotechnology with the City of Philadelphia.

Evelyn Guo, M.D., M.B.A., M.S.

Medical Director
Genmab

Medical director with 17 years of clinical development experience and 9 years of basic research experiences in oncology, autoimmunology, diabetes etc. Have years experience of FDA and EMA submission for newly developed medication.

Jinghua He, Ph.D., M.P.H.

Group Director of Real-world Value and Evidence
Johnson & Johnson Innovative medicine

Over 12 years pharmaceutical industry experience in providing real-world evidence strategies and solutions to address a variety of business needs throughout drug life cycles, with a focus on outcomes research and epidemiology.

Sue Hellie, M.D., M.B.A.

Head, General Medicine, Global Medical Affairs
Regeneron Pharmaceuticals

Sue Hellie is the head of medical affairs in general medicine at Regeneron. She is an experienced leader of broader commercial and medical affairs. Before this, she was the head of medical affairs in renal disease at AstraZeneca. Her well-established track of record and proven success in drug development made her a great leader in this field.

Andrew Jiang, M.B.A., M.S.

President
Aleon Pharma International, Inc.

Andrew Jiang is the Founder and President of Aleon Pharma International, Inc. and Aleon Pharma (Suzhou) Co. (Aleon), an award-winning regulatory consulting firm which has extensive experience in global pharmaceutical and biologics development, regulatory strategy, liaising with health authorities (FDA, NMPA, and EMA) and regulatory submissions (INDs, NDAs/BLAs, etc.). Since its establishment in 2010, Aleon has collaborated with many pharmaceutical/biotech companies and has played critical roles in the global development of multiple innovative drug candidates. Prior to founding Aleon, Andrew held director positions in global regulatory affairs at Bayer HealthCare, Novartis, Astellas, Pfizer, and other companies. He has over 25 years of direct experience liaising with major health authorities including FDA, NMPA, EMA, Health Canada and has held many formal meetings with the FDA as the company's lead representative. Andrew has led global regulatory teams through successful regulatory submissions of pharmaceutical and biological products in various therapeutic areas including oncology, cardiovascular & metabolic diseases, neurology, etc. He has received multiple corporate awards for outstanding professional performance.

Weimao Ke, Ph.D.

Associate Professor & Associate Department Head, Information Science
Drexel University

Weimao Ke is an Associate Professor in Information Science at Drexel University's College of Computing and Informatics. His research is focused on the analysis of large-scale unstructured data with the goal to identify what information is and quantify meaning from extensive, complex datasets. Prof. Ke's expertise spans a broad range of topics including decentralized information retrieval (IR) systems, distributed machine learning (ML), and complex networks. He is published in premier venues such as ACM Transactions on Information Systems (TOIS), ACM SIGIR, IEEE BigData, and Information Processing & Management (IP&M). His current agenda is centered on IR theory and its integration with large language models (LLMs) for optimizing predictive analytics, enhancing educational methodologies, fostering creativity, and ensuring the integrity of information.

Thomas Kim, J.D., M.S.

CEO
EpiVario Inc.

Thomas Kim is the President CEO of EpiVario. He is an experienced biotech executive and corporate attorney, and a registered patent attorney. Prior to EpiVario, he served as SVP and Corporate Secretary for public biopharmaceutical company, Inovio Pharmaceuticals, where he built a global biotechnology patent portfolio, led the company through various MA transactions, and closed several licenses and partnering deals with large pharmaceutical companies.

Anna Georgieva Kondic, Ph.D., M.B.A., M.A., B.S.

Head Pharmacometrics
BMS

Anna Kondic, a native of Bulgaria, holds a PhD in Mathematics from Duke University and MBA with specialization in negotiations from Stern School of Business, NYU. Anna has more than 25 years of experience in mathematical modeling in the life sciences with projects spanning different therapeutic areas (oncology, women's health, cardio vascular), translational pharmacology and toxicology and applications requiring both mechanistic, statistical and health economic modeling approaches. Anna is very passionate about crafting pragmatic solutions to different questions, including dose and patient selection, as well as portfolio prioritization using different decision analytics approaches. Anna is a competitive masters artistic swimmer and loves traveling, allowing her to meet new people, learn about different cultures and practice different languages.

Ganhui Lan, Ph.D.

Vice President, Machine Learning & AI
Pfizer

Ganhui Lan is an accomplished business and technical leader in Machine Learning and Artificial Intelligence with extensive experience building data-driven teams and driving Data Science and AI/ML innovations across multiple industries and organizations. He currently serves as the Vice President of Machine Learning & AI at Pfizer, focusing on delivering disruptive solutions to boost effectiveness of commercial operations.

Ganhui's other professional experiences span various industries including Johnson & Johnson, Covance (currently LabCorp), Elsevier, Amazon, and IBM.

Ganhui has a PhD in Computational and Theoretical Biomechanics & Biophysics from Johns Hopkins University and a BS in Mathematical and Applied Mechanics from Peking University.

Dave Latshaw, Ph.D., M.B.A.

CEO & Co-Founder
BioPhy

Dave received his Ph.D. in chemical and biomolecular engineering from North Carolina State University and got his MBA at Wharton. His career started at The Janssen Pharmaceutical Companies of Johnson and Johnson working in a group that oversaw the manufacturing of large molecule antibodies. Dave also led flagship programs for the company's AI Advanced Center of Excellence and enabled J&J's billion dose commitment during the COVID pandemic. Dave was inducted into Frontiers of Engineering, an organization created by the National Academy of Engineering to recognize top early-career engineers.

Han Li, Ph.D.

CEO
NovaRock Biotherapeutics, Ltd

Dr. Han Li presently serves as the Co-founder and CEO of NovaRock Biotherapeutics Ltd., a clinical-stage biotechnology company in New Jersey. NovaRock is dedicated to the discovery and development of novel antibody therapeutics for the effective treatment of cancer and immune diseases. Before founding NovaRock, Dr. Li amassed over 25 years of experience in biologics R&D at Sanofi, BMS, and others. Dr. Li earned her B.S. degree from Peking University, completed her Ph.D. at Colorado State University, and underwent post-doctoral training at the National Jewish Center in Denver, Colorado.

Ying Li, Ph.D.

Director of HEOR
Regeneron Pharmaceuticals, Inc.

Dr. Li stands at the forefront of medical informatics research, with a professional journey spanning over 14 years. Her expertise lies in data mining, machine learning, and natural language processing, focusing on their practical applications in addressing significant healthcare-related challenges. Dr. Li specializes in extracting, integrating, and transforming both structured and unstructured data into valuable and actionable insights. These data sources include electronic health records (EHRs), claims databases, literature, social media platforms, the internet, and internally generated data from corporations. After obtaining her PhD in Biomedical Informatics from Columbia University, she served at IBM Research in the Center for Computational Health for five years. During her tenure, she played a pivotal role as a research staff member, spearheading the Watson for Patient Safety research prototype. In recent years, Dr. Li has been serving as a Director of Health Economics and Outcome Research at Regeneron Pharmaceuticals. Her work primarily centers on using real-world data to address a variety of business needs within the comprehensive drug development process.

Yunsong (Frank) Li, Ph.D.

Executive Director
WuXi Biologics

Dr. Frank (Yunsong) Li currently serves as an Executive Director, Head of US PD & MSAT at WuXi Biologics, based on Cranbury, New Jersey and King of Prussia, Pennsylvania. He oversees all WuXi Biologics development laboratories and Manufacturing Sciences and Technology (MSAT) teams in the USA. Before joining WuXi Biologics, he held the position of Senior Director, Product Development at Catalent Biologics in Bloomington, Indiana. During the COVID-19 pandemic, He led the Catalent MSAT team tech transferred the Moderna and J&J drug product manufacturing process at an unprecedented speed for COVID-19 vaccines and enabled the successful production of hundreds of millions of doses of those vaccines to fight the pandemic. Before his role at Catalent, Frank worked at Merck & Co. and Amgen with increasing responsibilities.

Frank has more than 17 years of biologics process and product development experience with both CDMO and large pharmaceutical companies. Besides his current responsibilities at WuXi Biologics, Frank also serves as an Adjunct Professor in The Department of Industrial and Molecular Pharmaceutics at Purdue University, teaching graduate students and Pharm D. students about biologics drug product development.

Dr. Frank Li holds a Ph.D. in Pharmaceutical Chemistry from the University of Kansas, Lawrence, Kansas, and a M.Sc. in Chemistry from the University of British Columbia, Vancouver, Canada, and a B.Sc. with Honor in Chemistry from Peking University, Beijing, China. He has published over 14 peer-reviewed publications.

Jiang Liu, Ph.D.

Associate Director for Therapeutic Review
FDA

Dr. Jiang Liu is the Associate Director for Therapeutic Reviews of the Division of Pharmacometrics, Office of Clinical Pharmacology, OTS/CDER/FDA. Dr. Liu received his Ph.D. in pharmaceutical sciences and Master in statistics from the University of Florida. He joined the FDA as a pharmacometrics reviewer 15 years ago. Dr. Liu had also served as a QT-IRT scientific lead for three years and a pharmacometrics team leader for four years before taking his current role. He is overseeing pharmacometrics review activities focusing on oncology, immunology, rare diseases, etc.

Asha Mahesh, M.S.

Sr. Director R&D Data Science and Digital Health
Johnson & Johnson

Over 20 years of experience in the bio-pharmaceutical industry leading high performing teams focused on a variety of areas including drug discovery, development and commercialization.

Experience in leading global scale transformations & complex portfolios, finding opportunities for strategic initiatives, and translating scientific and medical questions into innovative solutions to drive successful patient outcomes.

Co-led cross-industry and public consortiums to develop common data standards, consistent evidence generation, share & co-develop the best practices in multi-modal data management and federated learning models.

Experience in federated learning, data science, clinical

& scientific data management, data governance, regulatory, security, privacy, and ethics to navigate through complexities and "connect the dots", craft compelling narratives and create strategies that lead to decisive action.

Haichen Nie, Ph.D.

Associate Director
Teva Pharmaceuticals

Haichen Nie is working for Teva pharmaceuticals as an Associate director, leading a team to develop formulations for biological drug products and to evaluate the application of novel excipients in different dosage formation. Before joining Teva, Haichen worked for 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. He has broad experience in preclinical development, formulation and process optimization, and commercial manufacturing. He is specialized in physicochemical characterization, spectroscopic analysis, oral and sterile drug product development. Haichen has over 40 peer-reviewed publications on pharmaceutical journals and invented several patents since 2016. In 2022, Haichen became an adjunct assistant professor at Purdue University College of Pharmacy. As a volunteer, Haichen serves on the Editorial Advisory Boards of AAPS PharmSciTech, drug development and industrial pharmacy, and Journal of pharmaceutical sciences. He also works as an expert committee member for US Pharmacopeia and leads the AAPS excipient community as the chair.

Alex Qiu, Ph.D., M.D.

Executive Director, TA Lead for Oncology Solid Tumor Early Assets, External Relationship
BMS

Over 30 years' experience in the oncology field from clinical practice, basic research, preclinical drug discovery, clinical development, and drug safety. Over 23 years pharmaceutical industrial experience ranging from drug discovery, clinical development, pharmacovigilance, and NDA & BLA submission. Therapeutic area included oncology, autoimmune-diseases, cardiovascular diseases, dermatology, and infectious diseases, led or oversighted more than 50 projects in the clinical development stage ranging from Phase I to phase III, and post-marketing stage. As the lead safety physician involved three successful submission and gained FDA approval: Dostarlimab: PD-1 antibody to treat endometrial carcinoma treatment in 2021, Pemazyre: FGFR2 inhibitor to treat cholangiocarcinoma in 2020. Citacel (Car-T), to treat multiple myeloma 2022. Educations:

- MD, JiangXi Medical College, PR. Of China
- Ph.D, Wake Forest University, Bowman Gray School of Medicine, North Carolina, USA
- Post doctor: University of California, San Francisco, USA

Boshu Ru, Ph.D.

Director, Real-world Data Analytics and Innovation, MRL CORE Real-world Evidence
Merck & Co.

Dr. Boshu Ru is a Director and Principal Scientist in the Real-world Data Analytics and Innovation team of Merck Research Lab Center for Observational and Real-world Evidence. He is leading a team of data scientists to support RWE generation and Data Science innovation for Merck's products in cardiovascular, metabolic, antibiotics, virology, and other general medicine therapeutic areas. Before Merck, he worked as a senior data scientist at Sema4 (now GeneDx). Dr. Ru is an expert in designing outcome research and building analytics models with real-world data. He completed the Ph.D. training in computing and information systems program at the University of North Carolina at Charlotte in 2018. Dr. Ru grew up in China and completed college at Xiamen University.

Chelsea Changxia Shao, Ph.D., M.P.H.

Senior Director of Epidemiology
Merck

Chelsea Shao is a Senior Director in the Biostatistics and Research Decision Sciences (BARDS) - Epidemiology at Merck & Co, Inc., Rahway, NJ. She has over 13 years of experience in the fields of Epidemiology, Precision Medicine, and Outcome Research, with over 10 years in the pharmaceutical industry.

Fang Shen, Ph.D.

VP of 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 postdoctoral 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.

Jennifer Sheng, Ph.D., Pharm.D.

VP, Clinical Pharmacology & Pharmacometrics
Incyte

Dr. Jennifer (Jenny) Sheng, B. Pharm., PhD, is VP & Head of Clinical Pharmacology, PK and Pharmacometrics at Incyte Corporation. Jenny has over 20 years of industry experience in Clinical Pharmacology and Pharmacometrics (CPP), Modeling & Simulation, and Biopharmaceutics. At Incyte, she is accountable for the CPP function, across early and late-stage development, across Therapeutic areas, and across modalities. Dr. Sheng is co-leading the AL/ML focus group, across Discovery and Development. She had advocated the advancement and applications of AI/ML in Pharma/Biotech, being one of the founding members for MLAC (Machine Learning Advisory Committee).

Prior to joining Incyte, she worked at BMS, leading the CPP group in Hematology/Oncology/CART and founded the CPP function for BMS China. She has supervised and/or supported ¿25 INDs/CTAs and ¿20 NDAs/BLAs submissions/approvals in the US, EMA and other countries and has substantial experience of extensive and successful interactions with global regulatory agencies.

Professionally, Dr. Sheng has presented at major scientific congresses, at FDA workshops and has authored over 80 manuscripts/symposia/abstracts in peer reviewed journals, with serval of them recognized as "the mostly cited" by various journals. Jenny earned her B.S. degree in Pharmacy from Peking University and her Ph.D. in Biopharmaceutics from the University of Michigan.

Sujatha Sonti, Ph.D.

VP, Drug Product Development, Sr. Scientific Fellow
GSK

Sujatha Sonti is VP, Drug Product Development and GSK Senior Fellow based at the UP site in Philadelphia. In her current role she leads a global team of outstanding scientists across disciplines including formulation, packaging, biopharmaceutics, engineering, modelling and process analytics to develop innovative and robust, patient centric medicines. This team is accountable for the design, development and industrialisation of drug products (Oral, Sterile and Inhaled) and their manufacturing processes for all GSK small molecule and biopharmaceutical products. Sujatha obtained a Bachelors in Pharmacy from the University of Mumbai, India and received her Ph.D. in Pharmaceutical Sciences from West Virginia University. Her graduate research focused on the delivery of large molecules: antisense oligonucleotides and gene therapy for the treatment of lung inflammation. Prior to GSK, Sujatha has previously worked at Avon Products, Inc, Ionis Pharmaceuticals, SkinMedica, Inc (a division of Allergan) and Medicis Pharmaceuticals, where she worked on the development of both prescription and consumer care products. Through these opportunities, she has gained over 24 years of product development experience and has had the incredible fortune of launching several Prescription/Cosmetic/OTC products.

Leon Liying Sun, Ph.D., M.D.

Chief Medical Officer
Feirui Biopharmaceutical Corp

Leon Sun, MD, PhD
Now served as:

1. ICH E15 Guideline Expert Group
2. Chief Medical Officer for: Hubei Feirui Pharma, Shanghai Baijibodi Biotech, Jiangsu Haiyi Biotech, Beijing Luorui Biotech
3. Chief Strategist, Caoshan Capital
4. Visiting professor in Beijing Technology University

5. Strategic advisor in Guizhou Scientific Academy
6. Published more than 130 papers in peer-reviewed journals and earned 1 patent

Was served as:

1. FDA: Senior reviewer/Lead Epidemiologist
2. NIH/NCI (National Cancer Institute/National Institutes of Health): Project Director/Statistician
3. Duke University: Director of Prostate Disease Information Center
4. Uniformed Services University of Health Sciences: Director of Trauma Molecular Biology Laboratory
5. Cardiovascular surgeon before 1992

Products developed:

- <eCTD System>for submissions to NMPA, FDA, EU, TGA and CA
- <A Decision-making System Optimized for Tumor Diagnostic and Treatment>developed based on more than 10 million of real cancer cases

Weiyong Sun, Ph.D., M.D., M.B.A.

CBO
Hansoh Pharma

Dr. Sun, serving as the Chief Business Officer (CBO), currently leads Global Business Development and Alliance Management at Hansoh Pharmaceutical Group. Over the past three years, he and his team have accomplished over 20 licensing and collaboration deals, including two recent outbound licensing agreements with GSK. Dr. Sun also plays a pivotal role in supporting Hansoh R&D by evaluating and accessing new technologies, platforms, and modalities. Before joining Hansoh, Dr. Sun dedicated 19 years to Daiichi Sankyo, where he spent the initial five years in R&D, contributing to activities ranging from target discovery to clinical development. Transitioning to the Business Development division, he successfully identified, evaluated, and negotiated numerous partnership opportunities. Dr. Sun holds an MD from Peking University Medical School, as well as master's and doctoral degrees in Cell Biochemistry from the University of Tokyo. Additionally, he earned an MBA from Columbia Business School.

Leon Tang, Ph.D., M.S.

Founding Partner
InScienceWeTrust Advisory & ISWT-Community

Leon 'Jun' Tang, PhD is the founding partner of InScienceWeTrust BioAdvisory, a business development company focused on the East-West cross-border partnerships in the pharmaceutical industry. Dr. Tang is also the founder of InScienceWeTrust Community, which has more than 2,000+ members from Asian biotech community.

Dr. Tang serves as a scientific advisor to Mianus Capital, a boutique US-based healthcare PE/VC fund currently focused on ophthalmology. He is also an advisor to BioSpark, an Asian biotech professional's association based in Massachusetts.

Previously, Dr. Tang was a senior director of BD Search & Evaluation at Shanghai Henlius Biotech, a public biotech listed on Hong Kong Stock Exchange, a biotech sell-side analyst at Barclays Investment Bank, and a senior manager/senior analyst at the philanthropic venture fund of Cancer Research Institute of New York.

Dr. Tang has published 50+ academic papers, some of which are in Nature Reviews Drug Discovery, Lancet Oncology, Science Translational Medicine, Nature Communications, Science Advances, PNAS, etc. Dr. Tang received his bachelor's degree from Tianjin University, master's degree from Nankai University, PhD from Icahn School of Medicine of Mount Sinai, and postdoctoral training at Memorial Sloan Kettering Cancer Center.

Haijun Tian, Ph.D.

Associate Vice President of Value, Evidence and Outcomes
Eli Lilly

Haijun Tian is currently working as the Associate Vice President of RWE Strategy at Eli Lilly. He is leading the strategic RWE capabilities building to drive current and future real-world evidence generation. Prior to that, he worked as the Real-World Evidence Executive Director at Novartis. His most recent work at Novartis focused on establishing RWE capabilities in China. He served as an external expert to develop the Guidance on Design and Protocol Development of Real-World Evidence Studies (RWS) for Drugs, released by the China National Medical Product Administration in July 2022.He has many years of RWE experience in multiple disease areas, and has managed RWE strategies and plans for multiple innovative medical prod-

ucts to support drug development, product launch and life cycle management. Before joining Novartis, he worked as Senior Statistician at IQVIA US. He has led many large registries, prospective/retrospective RWE studies and published dozens of peer-reviewed manuscripts, covering various RWE topics across multiple disease areas.

Haijun Tian received a Bachelor of Arts in Political Science and Public Administration, Minor in Law, and a Master of Arts in in Public Management from Peking University; and a PhD in Policy Analysis from the Pardee RAND Graduate School.

Fei Wang, Ph.D.

Professor of Population Health Sciences
Cornell University

Fei Wang is currently a tenured Professor of Health Informatics in Department of Population Health Sciences at Weill Cornell Medicine (WCM). His research interest is machine learning and artificial intelligence in biomedicine. He is the Founding Director of the WCM Institute of AI for Digital Health (AIDH). Dr. Wang has published on major AI venues including NeurIPS, ICML, AAAI and KDD, as well as major medical venues including Nature Medicine, Annals of Internal Medicine and JAMA Internal Medicine. Dr. Wang is an elected fellow of American Medical Informatics Association (AMIA), American College of Medical Informatics (ACMI) and International Academy of Health Sciences and Informatics (IAHSI), and a distinguished member of Association for Computing Machinery (ACM). Dr. Wang's research has been extensively funded by federal agencies including NIH, NSF and ONR, private foundations including MJFF and AHA, as well as industries such as Amazon, Google, Boehringer Ingelheim, Regeneron and Sanofi.

Heidi Wang, Ph.D.

CEO
OBI Pharma, Inc.

Dr. Heidi Wang is an experienced drug development expert with Pharmaceutical Industry experience. With deep expertise in Oncology, Virology, and other therapeutic areas, Heidi led and contributed to shaping the company's strategy and identify, assess, and mitigate risks proactively.

Before joining OBI Pharma as the CEO in June 2023, Heidi had a close to 30-year career at Bristol-Myers Squibb (BMS, a Fortune 500 company) leading teams in the US headquarter and in multiple countries, including China. Heidi has a proven record of working or leading teams to obtain approvals for 9 New Molecule Entities, many were first-in-class drugs, as well as numerous supplemental applications worldwide.

When in BMS, Heidi had a chance to transform company's process and mindset to optimize company's portfolio acceleration, enable global submissions and approvals of life saving medicines, and shape company's 2030 China strategy, etc. When working as the BMS China regulatory head and acting R&D China head, Heidi delivered successfully four new medicines to patients while navigating the complicated regulatory environment.

Now as the CEO of OBI Pharma, Heidi continues what she did at BMS to change the company's culture, mindset, and processes, and provide leadership to optimize OBI's portfolio for patients.

Liman Wang, Ph.D.

Director of Global Regulatory Affairs
Merck

Dr. Liman Wang is Director of Global Regulatory Affairs, Oncology at Merck. In her current role, she is a global regulatory lead responsible for development and implementation of worldwide regulatory strategy in the oncology therapeutic area. She successfully led her team to achieve global filings and approvals in the US, EU, China, Japan and most of the world countries. Prior to her role in oncology, Dr. Wang was a Director in the Global Regulatory Affairs Vaccine and Infectious Disease therapeutic area for four years. She supported licensure of ERVEBO® (Ebola vaccine) in the US and EU, and was the global regulatory team lead for various vaccine products or pipeline candidates. Prior to joining the regulatory affair department in 2017, Dr. Wang worked in Merck's BioProcess R&D organization and took on increasing responsibilities over 16 years as program analytical lead and cross-functional team lead for development of various vaccine and biologics pipeline products. Dr. Wang received her B.A. in Chemistry from the Coe College in Cedar Rapids, IA, and her Ph.D. in Chemistry from the University of Wisconsin-Madison.

Shawn Shouye Wang, Ph.D.

Founder and Board Director at Chinese Antibody Society and Senior Director at WuXi XDC

Shawn Shouye Wang was the founding president of Chinese Antibody Society, and is currently a Director of Board of Directors of the society. He is a CMC Lead and a Senior Director at WuXi XDC. Prior to his transfer to WuXi XDC in September, 2023, he had been working as a CMC Lead at WuXi Biologics (the parent company of WuXi XDC) for nearly seven years on many early stage integrated CMC (Chemistry, Manufacturing, and Control) projects for IND filing and late stage projects for BLA filing with US FDA, China NMPA, and/or other countries' regulatory agencies. He has worked on diverse modalities of biologics and vaccines including monoclonal antibodies, bispecific antibodies, antibody-drug conjugates (ADCs), Fc fusion proteins, and enzymes. In addition, he has been supporting WuXi Biologics' business expansion in the US, in particular the establishment of new sites in the US. He was Analytical Head of King of Prussia, PA site of WuXi Biologics in 2019. He led the Biologics CMC Leadership training program of WuXi Biologics during 2017-2010, and also led in 2022 series biologics CMC trainings for global sites in support of global expansion of WuXi Biologics. Prior to WuXi Biologics, he worked for Bristol-Meyer Squibb and Emergent Biosolutions with focus upon analytical development. He obtained his PhD in protein chemistry from University of Science and Technology of China followed by postdoc trainings in Sweden and US.

Michele Washko, M.B.A., M.A., B.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, an MBA from Penn State University, and a certificate in Executive Leadership from M.I.T.

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.

Zhicheng (Patrick) Xiao, Ph.D.

Director of CMC

GSK

With a solid technical background and a wide range of interdisciplinary experience, I am a skilled project leader in small and large molecules drug product development. I have over 16 years of experience in CMC development of various therapeutic modalities, such as small and large molecules, peptides, mAbs, RNAi, and gene therapy. I have a proven track record of delivering complex projects successfully, optimizing time and budget resources, and developing effective R&D strategy and operations in global pharma companies. I am highly competent in leading and influencing cross-functional teams, and managing communication with internal and external stakeholders. I always demonstrate integrity, resilience, and excellence in my work and beyond.

Bing Yang, Ph.D., M.B.A.

Co-Founder and CEO
OnCusp Therapeutics

Dr. Bing Yuan is a seasoned business executive and entrepreneur with 20+ years of biopharma experience, made significant contributions to 14 approved global oncology brands during his career, including blockbusters such as Keytruda and Glivec. In early 2021, he co-founded OnCusp Therapeutics, a New York based clinical stage biotech company dedicated to transforming cutting-edge preclinical innovation into clinically validated treatments for cancer patients worldwide. He successfully built the team, developed a portfolio of innovative assets, and raised a total of $139M in Seed and Series A financing rounds supported by world leading biotech investors.

Before co-founding OnCusp, he was Chief Strategy and Business Officer at CStone Pharmaceuticals, achieved 10+ deals with leading global companies such as Pfizer, Bayer, Blueprint, Agios and EQRx. As a senior executive from the beginning, he helped to build CStone from startup to successful IPO in just three years and managed over 10 different business functions.

Prior to joining CStone in 2016, he spent 22 years in the USA. He was Global Lead of Oncology BDL at Merck (MSD), led or contributed to 30+ licensing, MA and Keytruda clinical collaboration deals. Before Merck, he held various global commercial positions with increasing responsibilities at Novartis Oncology, most recently as Executive Director and Head, Brand Life Cycle Strategy. He also played key roles in new product strategy, business development and global launch of a lung cancer drug. He also used to be Global Oncology Marketing Lead at Eisai, managing the oncology portfolio.

Tong-yuan Yang, Ph.D., M.D.

Senior Scientific Director, Preclinical Sciences and Translational Safety
Johnson & Johnson Innovative Medicine

Dr. Tong-yuan Yang currently is Senior Scientific Director at Preclinical Sciences and Translational Safety, Janssen Research and Development, LLC, the pharmaceutical sector of Johnson & Johnson. He has over twenty years of experience in biopharmaceutics ranged from drug discovery, development to market approval. He manages a group of scientists to develop and validate immunological and biochemical assays to support characterizing pharmacokinetics (PK) and immunogenicity of biologics, CAR-T and gene therapy products in nonclinical and clinical settings. He is an active member of the American Association of Pharmaceutical Sciences. He received his medical degree from Peking Medical University (Now Peking University Health Science Center) and Ph.D. in Molecular Virology from Pennsylvania State University College of Medicine where he also holds an adjunct professorship at Department of Pharmacology. Contact: `tyang9@its.jnj.com`; `https://www.linkedin.com/in/tong-yuan-yang-69008b8/`

Zhen Yang, Ph.D.

Director of Global Business Development & Alliance Management
Hansoh Pharma

Dr. Yang is currently Director of Global Business Development and Alliance Management with Hansoh, one of China's leading pharmaceutical companies. Zhen is at the forefront of driving the company's strategic business development initiatives. He has closed more than 10 deals since he joined Hansoh in 2019. Before Hansoh, Dr. Yang worked for Merck, where he led teams focusing on the preclinical and clinical development of various projects. Transitioning from a scientific role, Zhen later worked as a biotech equity analyst in an Investment Bank to broaden his expertise. Dr. Yang received his Ph.D. from the University of Houston, colleague of Pharmacy.

Lixia Yao, Ph.D.

President and CEO
Polygon Health Analytics LLC

Dr. Lixia Yao is the founder and CEO of Polygon Health Analytics LLC, which specializes in developing high-quality real-world data (RWD) and real-world evidence (RWE) in disease areas with pressing unmet medical needs.

With a PhD in Biomedical Informatics from Columbia University, Dr. Yao previously worked as the director of Real-world Data Analytics & Innovation at Merck and an Associate Professor in Biomedical Informatics at Mayo Clinic. She has cultivated a deep understanding of RWD and authored 60+ peer-reviewed articles on prestigious journals such as Nature Biotechnology, Genome Research, and Drug Discovery Today with a H-index of 20.

Dr. Yao received the Career Development Award in Biomedical Informatics from the National Library of

Medicine (2016-2019). She is also a Fellow of the American Medical Informatics Association (FAMIA) and served as the Chair of the AMIA KDDM working group (2020-2022). Currently, she holds the additional roles of Member Engagement Co-Chair for the Oncology Special Interest Group at the Professional Society for Health Economics and Outcomes Research (ISPOR), Director of Business Insights & Analytics at SAPA-GP, and Adjunct Associate Professor in the Department of Health Services Administration and Policy at Temple University.

Zhifeng Yu, Ph.D.

Director of Assay & DEL Screen
WuXi AppTec

Zhifeng Yu, Ph.D., is a biochemist with a background from the Chinese University of Hong Kong and postdoctoral training at Baylor College of Medicine (BCM). As an Assistant Professor at BCM, Dr. Yu played a pivotal role in establishing BCM's DNA-encoded library (DEL) technology and leading drug discovery campaigns. Currently serving as the Director of Assay & DEL Screen at WuXi AppTec, Dr. Yu leverages 9 years of DEL experience to drive the development of cutting-edge DEL technologies and oversee the DEL service platform in the United States.

Aria Zhang, Ph.D.

BD Executive II
GenScript USA Inc.

Aria joined GenScript in 2017 and is currently leading the business development team for GenScript recombinant protein and antibody services. Before joining GenScript, she did her postdoc research for 9 years at University of Pittsburgh working on protein function and structure. She obtained her Ph.D. degree in Biomolecular Sciences studying 3D structure of membrane protein. Over the years, she produced 10 first author publications.

Yun Zhang, Ph.D.

Drug Safety Team Lead (DSTL) of Drug Safety R&D (DSRD)
Pfizer

Yun Zhang (YZ), PhD, DABT, is a full-time Drug Safety Team Lead (DSTL) at Pfizer since 2017. Dr. Zhang is an experienced drug developer, as a Project Toxicologist, with over 20+ years of comprehensive experience in nonclinical drug safety assessment in the biopharmaceutical industry (CRO and large pharmaceutical companies). He started his toxicology career with the Southern Research (SRI, a CRO) in 2002 as the SD/Toxicologist on a variety of GLP toxicology studies designed to evaluate nonclinical safety of drug candidates (small molecules, biologics, vaccines, gene therapy, and siRNA). After he switched to large pharmaceutical companies in 2004 (Merck, GSK China, and Pfizer) as part of the drug development team, he has been involved in the entire process of the drug discovery and development and gained broad working experience/knowledge of the drug discovery/development process and knowledge of regulatory processes and guidelines. He has served as the Safety Assessment (SA) Representative on multiple early and late drug development project teams with demonstrated capability of integrating information across drug development disciplines and influencing program/project directions. As the SA Rep, he is responsible for non-clinical safety program strategy, designing/planning non-clinical safety studies, toxicity risk management, preparation of toxicology regulatory submissions and addressing potential regulatory issues, and participating for review/evaluation of potential licensing candidates. In addition, he has been actively involved in the SAPA, AACT, and RDPAC activities.

Track Leads & Session Chairs

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 currently is a Scientist at Cell Therapy department of Johnson & Johnson Innovative Medicine Research and Development. He is 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 Development, LLC supporting Immunology and Oncology pipelines and contributing to 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 Immunology from Ben-Gurion University, Israel and conducted his postdoctoral training at University of Pennsylvania. He serves as Scientific Discovery tack lead in SAPA-GP AC2024.

Dong-Jing Fu, M.D., Ph.D.
Senior Director of Neuroscience
Johnson & Johnson Innovative Medicine

Dr. Fu is a Senior Director in Neuroscience Clinical Development at Janssen Research and Development. Currently she is the Clinical Leader of the intranasal esketamine development program in patients with treatment resistant depression and major depression at imminent risk for suicide. She is also a clinical leader for several compounds in early stage of development for neuropsychiatric disorders.

Since joining Johnson & Johnson in 2005, Dr. Fu has worked on pivotal studies for the treatment of depression, suicidality, schizophrenia, and schizoaffective disorder. She has held positions within Janssen R&D and Medical Affairs directing global clinical trials, leading pharmacogenomics projects in psychiatry, and overseeing a program to support independent medical education in psychiatry. Dr. Fu had prior positions with Eli Lilly and Sequenom involving research and technology development for precision medicine. Dr. Fu has authored publications focused on clinical and pharmacogenomic research of psychiatric diseases and treatments, scale validations, and technology development.

Dr. Fu received her PhD in biochemistry from Boston College and a MD from Beijing Medical University.

Evelyn Guo, M.D., M.B.A., M.S.
Medical Director
Genmab

Medical director with 17 years of clinical development experience and 9 years of basic research experiences in oncology, autoimmunology, diabetes etc. Have years experience of FDA and EMA submission for newly developed medication.

Zak Huang, M.D.

Vice President of US Regulatory Affairs
Hansa Biopharma

Zak Huang is a highly accomplished pharmaceutical executive with demonstrated success in delivering innovative regulatory and business strategies, as well as fostering a culture of sustained high performance.

Zak's industry career began in clinical development at Boston Scientific and Eli Lilly & Co. Transitioning to regulatory affairs, he drove science-based, solution-oriented, and globally aligned regulatory strategies. His leadership achievements in regulatory affairs and organizational management include navigating the regulatory landscapes in all major markets for new product development at companies such as Merck & Co, CSL Behring, Nimbus Therapeutics, Boston Scientific, and Hansa Biopharma. He has successfully filed and obtained approvals and clearance for numerous market and clinical applications. Furthermore, he has built and led regulatory affairs organizations, and served as the Head of CSL China R&D establishing and overseeing this multiple function research and development business unit.

Zak Huang holds a medical degree from Nanjing Medical University, and practiced medicine in China before transitioning to his career in the pharmaceutical industry in the United States.

Yufeng Li, Ph.D.

President-elect
SAPA-GP

Yufeng Li, PhD, most recently served as Executive Director of Clinical Development at Qilu Pharma, 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 Qilu, Yufeng has also served China biotech companies (Ascentage and Transcenta) 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 president elect for SAPA-GP for 2024-25 term.

Yali Liang, M.D., M.P.H., M.S.

Director
Jazz Pharmaceuticals

Yali Liang, MD, MS, MPH, Director of Clinical Pharmacology and Pharmacometrics, Jazz Pharmaceuticals

Yali is currently a Director in Global Clinical Pharmacology & Pharmacometrics at Jazz Pharmaceuticals. She serves as the clinical pharmacology and pharmacometrics expert for various assets across oncology and neuroscience portfolios at Jazz. Prior to joining Jazz, she worked at Bristol Myers Squibb as a clinical pharmacologist focusing on immuno-oncology therapeutic agents. Prior to BMS, Yali worked at Global Pharmacometrics at Pfizer. Yali has over 14 years of drug development experience in pharmaceutical industry and has contributed to the successful approval of Opdualag (nivolumab and relatlimab combination therapy), Opdivo, avelumab, ertugliflozin, ALO-2 etc.

Yali holds a MD and MPH from Tongji Medical University in China, MS in Pharmacometrics from University of Maryland, and MS in Pharmaceutical Science from University of Kentucky.

Bill Lu, M.B.A., M.S., B.S.

Principal Consultant
Forerun Advantage

Bill Lu is the founder and principal Consultant of Forerun Advantage since 2019. He helps Chinese biotech companies to understand US business culture and biotech ecosystem, establish business operations, and develop communication strategies. Previously, he was principal consultant of Queenberry Labs since 2013. Before moving into the field of 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). In addition, he led projects to build software for a helmet-based sport sideline assessment of concussions and mild cognitive impairments. He also built a clinical trial data management system for NIH-sponsored clinical trials. 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.

Haichen Nie, Ph.D.

Associate Director
Teva Pharmaceuticals

Haichen Nie is working for Teva pharmaceuticals as an Associate director, leading a team to develop formulations for biological drug products and to evaluate the application of novel excipients in different dosage formation. Before joining Teva, Haichen worked for 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. He has broad experience in preclinical development, formulation and process optimization, and commercial manufacturing. He is specialized in physicochemical characterization, spectroscopic analysis, oral and sterile drug product development. Haichen has over 40 peer-reviewed publications on pharmaceutical journals and invented several patents since 2016. In 2022, Haichen became an adjunct assistant professor at Purdue University College of Pharmacy. As a volunteer, Haichen serves on the Editorial Advisory Boards of AAPS PharmSciTech, drug development and industrial pharmacy, and Journal of pharmaceutical sciences. He also works as an expert committee member for US Pharmacopeia and leads the AAPS excipient community as the chair.

Bryan Tsao, Ph.D.

Manager of Life Sciences and 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.

Long Wang, Ph.D., M.D.

Vice President, Head of Vaccine Development
Takeda

Dr. Long Wang, MD, PhD, is currently Vice President, Head of Development at Takeda Vaccines. In his role, Dr. Wang oversees Clinical Development, Clinical Operations, Pharmacovigilance, Epidemiology, Medical Writing and Regulatory Affairs etc. Over his close to two decades of industry experience, Dr. Wang has worked for Merck, GSK and now Takeda in many different functions including Clinical Development and Regulatory Affairs. While he started his career on the pharmaceutical side, Dr. Wang has dedicated himself to the Vaccine field since 2012 and has successfully led the development and registration of many vaccine products.

Tong-yuan Yang, Ph.D., M.D.

Senior Scientific Director, Preclinical Sciences and Translational Safety
Johnson & Johnson Innovative Medicine

Dr. Tong-yuan Yang currently is Senior Scientific Director at Preclinical Sciences and Translational Safety, Janssen Research and Development, LLC, the pharmaceutical sector of Johnson & Johnson. He has over twenty years of experience in biopharmaceutics ranged from drug discovery, development to market approval. He manages a group of scientists to develop and validate immunological and biochemical assays to support characterizing pharmacokinetics (PK) and immunogenicity of biologics, CAR-T and gene therapy products in nonclinical and clinical settings. He is an active member of the American Association of Pharmaceutical Sciences. He received his medical degree from

Peking Medical University (Now Peking University Health Science Center) and Ph.D. in Molecular Virology from Pennsylvania State University College of Medicine where he also holds an adjunct professorship at Department of Pharmacology. Contact: tyang9@its.jnj.com; https://www.linkedin.com/in/tong-yuan-yang-69008b8/

Lixia Yao, Ph.D.
President and CEO
Polygon Health Analytics LLC

Dr. Lixia Yao is the founder and CEO of Polygon Health Analytics LLC, which specializes in developing high-quality real-world data (RWD) and real-world evidence (RWE) in disease areas with pressing unmet medical needs.

With a PhD in Biomedical Informatics from Columbia University, Dr. Yao previously worked as the director of Real-world Data Analytics & Innovation at Merck and an Associate Professor in Biomedical Informatics at Mayo Clinic. She has cultivated a deep understanding of RWD and authored 60+ peer-reviewed articles on prestigious journals such as Nature Biotechnology, Genome Research, and Drug Discovery Today with a H-index of 20.

Dr. Yao received the Career Development Award in Biomedical Informatics from the National Library of Medicine (2016-2019). She is also a Fellow of the American Medical Informatics Association (FAMIA) and served as the Chair of the AMIA KDDM working group (2020-2022). Currently, she holds the additional roles of Member Engagement Co-Chair for the Oncology Special Interest Group at the Professional Society for Health Economics and Outcomes Research (ISPOR), Director of Business Insights & Analytics at SAPA-GP, and Adjunct Associate Professor in the Department of Health Services Administration and Policy at Temple University.

Mike Yu, Ph.D.
Director Analytics and Insights
Johnson & Johnson Innovative Medicine

Mike Yu is a thought leader in the field of Data Science and Analytics, specializing in innovation and healthcare. With over 10 years of experience in data analytics team management, Mike has successfully developed and implemented data strategies for intelligent automation(IA), business intelligence (BI), artificial intelligence (AI), and GenAI. Throughout his career, Mike has led multiple data science capacity teams across diverse enterprise functions, including HR, finance, procurement, health services, and more.

Currently, Mike spearheads efforts in medical information intelligence, leveraging AI and business intelligence to enhance medical information, medical affairs insights, and customer engagements within Johnson and Johnson Innovative Medicine. Formerly, Mike held the position of Senior Manager of Advanced Analytics and Data Sciences at J&J Corporate Business Technology and Senior Manager of Analytics at J&J Global Finance, during his tenure, he received multiple accolades, including being a finalist for the 2021 Hackett Digital Award. Mike has a PhD degree on biomedical Studies from University of Pennsylvania and Bachelor of Science and Bachelor of Business Administration degrees from Peking University.

Yang Yuan, Ph.D.
Associate Director
Jazz Pharmaceuticals

Yang Yuan is currently the President of SAPA-GP (2023-2024) and Associate Director in Nonclinical Research & Development at Jazz Pharmaceuticals. She works as a nonclinical team lead in global drug discovery and development teams. 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 the global regulatory sciences group with increasing responsibilities. Yang has received her Ph.D. in medicinal chemistry with a focus on analytical chemistry from College of Pharmacy, University of Illinois Chicago. Yang has also received MS in Pharmacometrics from University of Maryland and currently is a candidate for Wharton MBA for executives.

Xinjun Zhang, Ph.D.
Associate principal scientist of Neuroscience Discovery
Merck

Xinjun Zhang currently serves as an Associate Principal Scientist and Biology Program Lead in the Neuroscience Discovery Department at Merck. Since joining Merck in 2018, he has been instrumental in identifying and validating novel drug targets for neuropsychiatric and neurode-

generative diseases. Xinjun has also played a key role in the development of innovative electrophysiological and molecular platforms to advance neuroscience drug discovery. Additionally, he leads Merck West Point LINK (Leveraging Internal Networks & Knowledge) team.

Prior to his role at Merck, Xinjun was a Research Associate at Memorial Sloan-Kettering Cancer Center, where his research focused on the functional connectivity and organization during neural development. With a rich academic background, Xinjun holds a Ph.D. in neurobiology from Fudan University and has authored over 15 research papers in prestigious journals.

Beyond his scientific contributions, Xinjun is an enthusiastic volunteer, actively involved in planning and coordinating events on pharmaceutical science and healthcare communications across various institutions. Notably, he leads this year's SAPA-GP Annual Conference and previously served as the IT team lead and Annual Conference co-lead.

Wei Zhou, Ph.D., M.D.

Associate Vice President of Value, Evidence, and Outcomes
Lilly

Wei Zhou is currently Associate Vice President and Head of Oncology, at Lilly Value, Evidence, and Outcomes (VEO). Before that, he was the Executive Director and Head of Oncology at Merck Epidemiology Department, Executive Director at Merck CORE Product Line, Head of Epidemiology Asia Pacific Unit at Merck, Director of Molecular Epidemiology at Pfizer Oncology, and Senior Epidemiologist at Merck. Wei was a Research Fellow/Research Associate/ Research Scientist at Harvard School of Public Health between June 1999 and December 2007. Wei is a Fellow, previous Board Member and Vice President for Finance, and co-lead of the Real-World Evidence Task Force of the International Society of Pharmacoepidemiology (ISPE).

Wei received his MD from West China University of Medical Sciences in 1994 and Ph.D. of Environmental Health from Shanghai Medical University in 1998. He was the recipient of the John E. Fogarty International Training and Research Program. He has published more than 90 peer-reviewed manuscripts and book chapters and served as a reviewer for various international journals. Wei has given numerous presentations and served as chair/co-chair at different international conferences and symposiums. Wei is a well-known expert in the fields of cancer epidemiology, molecular epidemiology, Outcome Research, and real-world evidence research.

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 on the joint CMC team for several of Teva's partnership products/projects.

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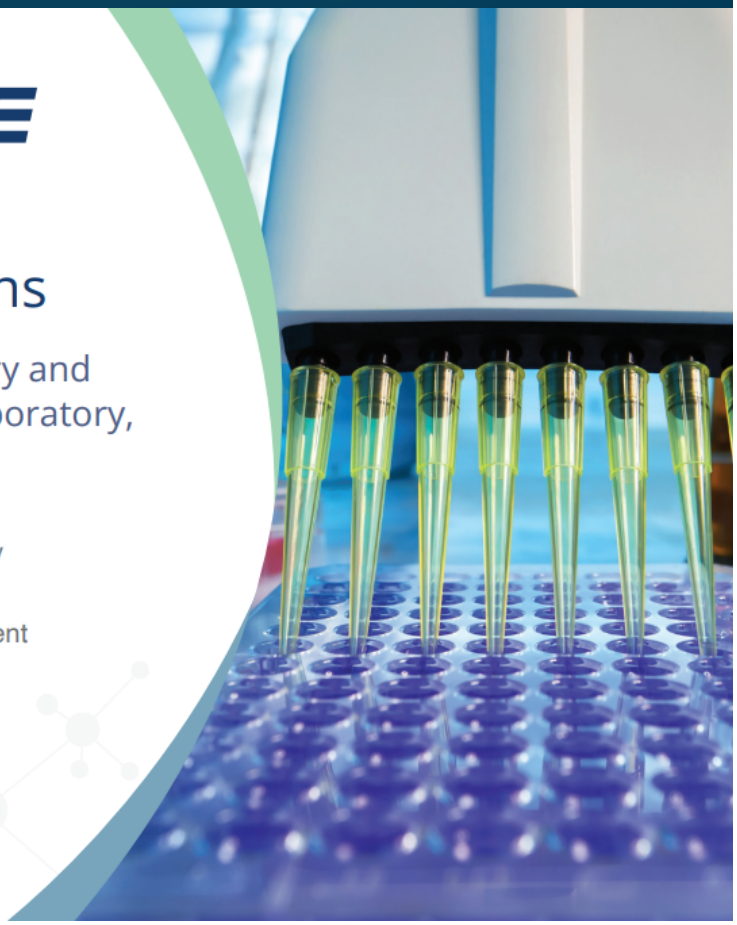

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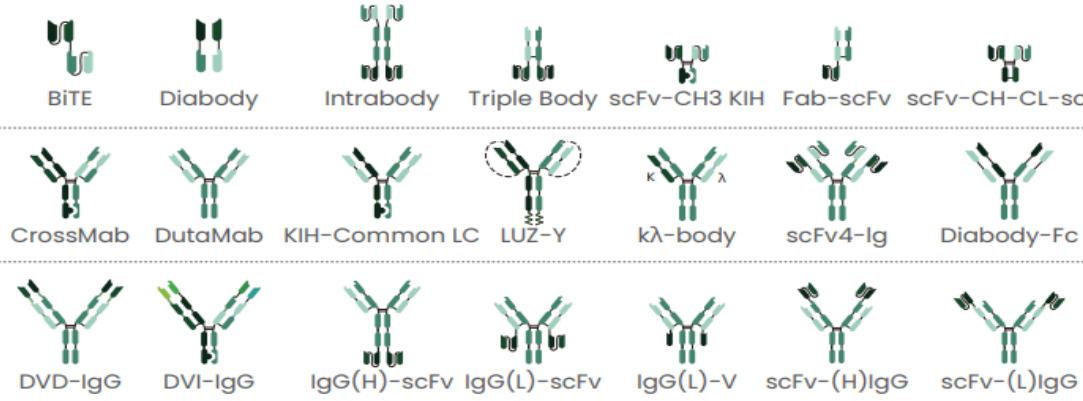

Our Experience with Diverse BsAb Formats (The bsAb nomenclature - DOI: 10.1016/j.molimm.2015.01.003)

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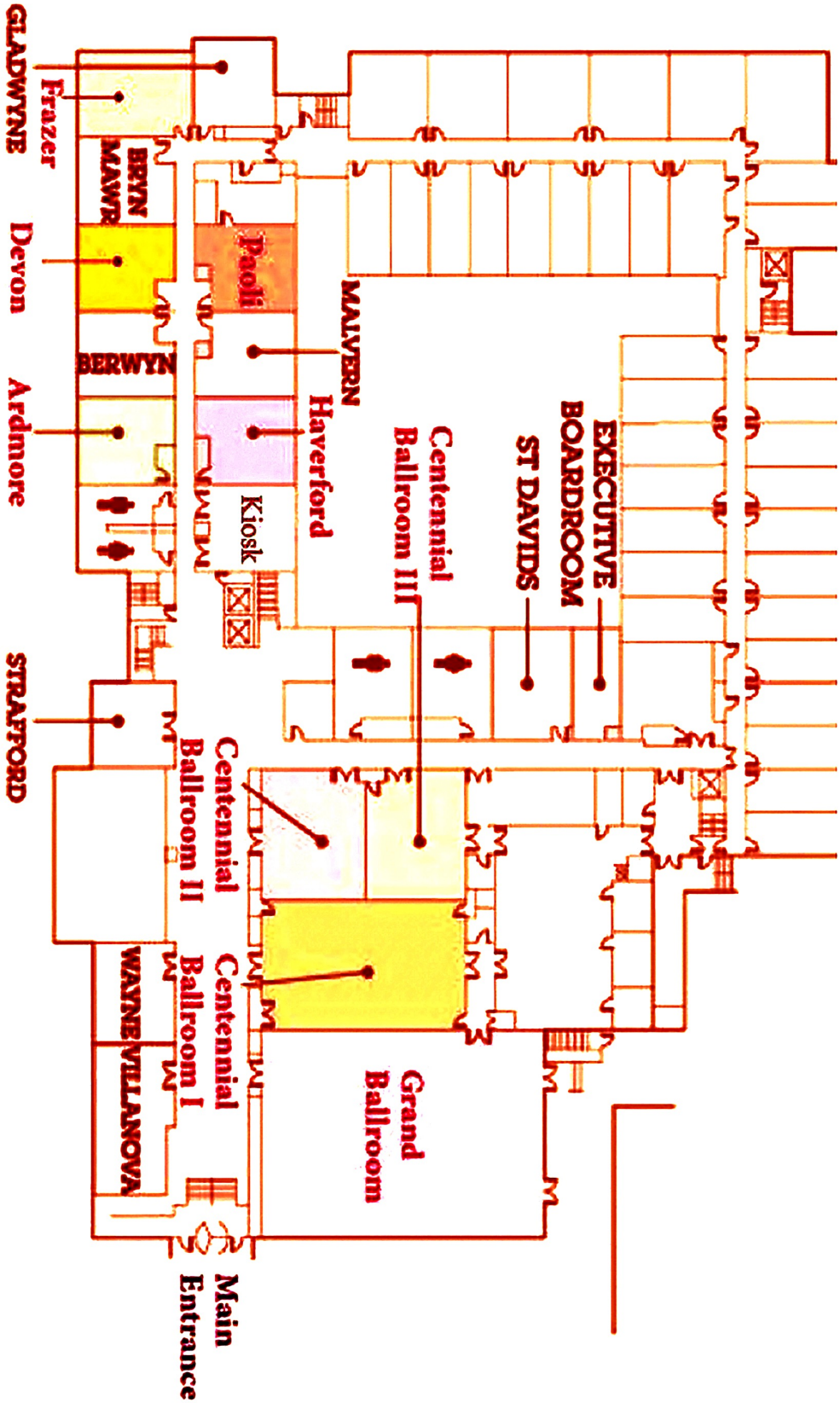
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