6TH KAPAL ANNUAL CONFERENCE

NOV 17-18, 2022

Gaithersburg Marriott Washingtonian Center | 9751 Washingtonian Blvd, Gaithersburg, MD 20878

Collaboration and Innovation in Biosciences

Organized by

KAPAL Korean-American Professional Association in Life Sciences

Cohosted by

Embassy of the Republic of Korea in the USA

KHIDI Korea Health Industry Development Institute

KPBMA Korea Pharmaceutical and Bio-Pharma Manufacturers Association

Diamond Sponsor

ISU ABXIS

KOREA GINSENG CORP

이수앱지스 신약본부 수시채용

이수앱지스 한국 최초의 바이오 항체 치료제 개발 경험을 바탕으로 세계적 수준의 면역항암 (Immuno-Oncology) 분야 신약개발을 목표로 연구개발에 정진하고 있습니다.
바이오 항암면역 신약개발을 함께 할 열정적이고 우수한 인재들을 모시고자 합니다.

모집부문	· 이수앱지스 신약본부 항암 면역 프로젝트 리더 (과장 이상급)
직무소개	· 바이오 항암면역 신약 과제 제안 및 운영 · 면역 항암 관련 in vitro 및 in vivo 효능 평가 업무
지원자격	· 면역학, 암생물, 약학, 생화학, 분자세포생물학 분야 박사 (박사 학위 후 3년 이상 연구 경험자)
우대사항	· 면역 또는 항암 관련 실무 연구 경험자 우대 · ADC 및 bi-/tri-specific antibody 구조기반 단백질 엔지니어링 전공/경력자 우대 · 의약품 개발 경험자 우대 (예: 비임상시험, IND 준비/제출) · Global Big Pharma 경력 및 Open Innovation 경험자 우대
조직소개	이수앱지스 신약본부 소속 리드검증팀은 항암면역 치료제 개발에 주력하고 있습니다. 자유롭고 창의적인 연구 분위기에 최신 연구 장비를 이용하여 새로운 타겟 발굴에서부터 비임상연구까지 진행합니다. 연구원은 원하는 프로젝트에 참여하여 개인의 역량을 최대한 발휘할 수 있는 경험을 할 수 있습니다. 그 외 신약본부 내 연구기획 업무, 대외 CRO 관리, Buisiness development 등 다양한 업무 경험의 기회도 제공됩니다.
접수기간	· 채용 완료시까지
지원방법	· 제출 서류 : 이력서 및 자기소개서 1부 · 접수 방법 : 이메일 접수 (인사팀 권지원대리 jeewon@isu.co.kr)
전형절차	서류전형 → 1차면접 → 2차면접 → 건강검진 → 채용확정
기타사항	· 회사 홈페이지: http://www.abxis.com · 문의처: 경영지원팀 권지원 (jeewon@isu.co.kr)

Dear Participants,

On behalf of the organizing committee, it is my great pleasure to welcome you to the 6th KAPAL Annual Conference (KAC) 2022.

In the last two years, we all experienced enormous global public health challenges posed by COVID-19, and the challenges remain. However, because of the expertise in every sector of life sciences not limited to biology, immunology, mRNA vaccines, and diagnostic development, we are able to return to an everyday life.

We are very excited to see this conference again in an in-person format. This event has become a platform for innovation and collaboration among Korean and American Bioscience companies, institutes, and scientists.

One of KAPAL's missions is to share and expand our knowledge of drug development and life sciences, and we are proud to have experts from a variety of areas within the biopharmaceutical sector, including lawyers, investors, regulators, researchers, and clinicians at the 6th KAC 2022.

I believe that every participant will have an excellent opportunity to establish potential collaborations and working relationships and to expand professional networks during the next two days.

I thank all the organizers who have worked tirelessly to create an amazing program with outstanding speakers.

The 6th KAC 2022 is aligned with the 12th Annual Bioscience and Engineering Symposium (ABES). The 12th ABES is organized by the NIH-Korean Scientists Association (KSA), which includes speakers with in-depth knowledge and experience in fundamental research who are always pursuing the next significant innovation and discovery.

This year's conference would not have been possible without the heartfelt support from organizations such as the Embassy of the Republic of Korea, the Korea Health Industry Development Institute (KHIDI), and the Korea Health Industry Development Institute (KPBMA). We sincerely thank all companies and organizations providing sponsorships to make these events successful every year. Also, we thank Mr. Jimmy Rhee, Special Secretary of the Governor's Office, who provided welcoming remarks to the 6th KAC 2022. Lastly, we thank all speakers, organizing committees, and participants and look forward to having a successful 6th KAC 2022 and 12th ABES.

Byung Ha Lee, Ph.D.
President, KAPAL

KAC + ABES 2022 PROGRAM

Program Chair: **Youngmi Ji, Ph.D.**

Thursday, November 17	
5:00 – 6:00 pm	**Registration & Networking**
6:00 – 6:20pm	**Opening Remarks** **KAPAL** Byung Ha Lee, Ph.D. (President, KAPAL) **Embassy of the Republic of Korea** Sang-Hee Kim (Minister Counselor for Health & Welfare) **The State of Maryland** Jimmy Rhee (Special Secretary, Governor's Office, Small, Minority & Women Business Affairs)
6:20 – 6:30 pm	**Group Photo**
6:30 – 7:30 pm	**Dinner**
7:30 – 8:00 pm	**Sponsor Presentation** **Psomagen: Your Trusted Multiomics Partner** Su Hong, Ph.D. (CEO, Psomagen) **ISU Abxis: Pioneer in new drug development** June Park (CSO, ISU Abxis) **Passion for Health** Luke Oh, Ph.D. (VP, Samsung Bioepis)
8:00 – 9:00 pm	**Keynote presentation I** Moderator: Hae-Young Ahn, Ph.D., RAC **Adopting Orphan Diseases-It Take a Village** Insook Kim, Ph.D. (Team Lead, Clinical Pharmacology, CDER, FDA) **Key IND-Enabling Nonclinical Studies for Rare Diseases: A Regulatory Perspective** Yangmee Shin, Ph.D. (Pharmacologist, CDER, FDA) **Q&A**
9:00 – 10:30 pm	**Networking & End of Day 1**

Friday, November 18

8:00 – 8:20 am

Registration / Breakfast

8:20 –9:00 am

Session 1. Company Presentation

Moderator: Eunkyung An, Ph.D.

Proteomics in Oncology Clinical Guidance
Sheeno Thyparambil, Ph.D. (mProbe)

Empowering Microbiome innovation and discovery – Take your research to the next level
Nur A. Hasan, Ph.D., MBA (EzBiome)

Redefining Cancer Therapies
Yong H. Park, MD (MedGene Therapeutis)

9:00 – 9:30 am

Keynote presentation II

Moderator: Byung Ha Lee, Ph.D.

Translation of Innovation into Medicine: MyoKardia Story
June H. Lee, MD FACCP (Venture Partner, 5AM Ventures
Board Director, Cincor Pharmaceuticals, Teneya Therapeutics, GenEdit, Eledon Therapeutics Scientific Advisory Board, Foresite Labs
Adjunct Professor, UCSF School of Medicine)

9:30 – 10:10 am

Session 2. BioTech Support Programs

Moderator: JongJoo Lee, Ph.D.

Government Support Programs in Fairfax County
Christy Youk, BS (International Business Investment Manager, Fairfax County Economic Development Authority)

Accelerating Drug Discovery to Commercialization from Korea to the U.S.
Ernesto Chanona, Ph.D. (Director of Business Development & Government Affairs, CSSi LifeSciences)

10:10 – 10:20 am

Coffee break

10:20 –11:20 am

Session 3. KHIDI USA K-Blockbuster

Moderator: Youngmi Ji, Ph.D.

Introduction of KHIDI USA K-Blockbuster Project
Soonmahn Park Ph.D. (Chief representative, KHIDI USA)

10:00 – 3:00 pm

ABES

Huons Group's successful US Entry
Jay Jaemyung Choi (CEO, Huons USA)

A2B2C to Digital therapeutics (DTx)
Sean G. Kang, MD, MPH (CEO, WELT corp.)

Successful Global Partnership with the K-Blockbuster Platform
Jung-hoon Woo, MS (CEO, BW Biomed LLC)

11:20 –12: 10 pm	**Session 4. Panel Discussion on Drug Development Strategy** **US Healthcare and Pharmaceutical Reimbursement Systems and Impacts on Your Development Strategy** **Ted Buckley, Ph.D.** Vice President, Government Affairs, Shionogi **Sarah Pitluck, MSc** Former Head/VP, Global Pricing & Reimbursement Strategy, Spark Therapeutics, Inc. **Leo Kim, Ph.D.** Formerly the Head of Business Planning and Operations (BPO), AstraZeneca Hematology R&D
12:10 –12:50 pm	**Lunch**
12:50 – 2:00 pm	**Session 5. Entering the US Market** Moderator: Jay Park, Ph.D. **Trends in BioPharma Market and Future Perspective** Michael Kim, MBA (Director, Baird) **Beyond location, location, location** **- Reshoring Best Practices** Pat Larrabee, MS (President and Founder, FacilityLogix, LLC. and Co-founder, Rapid Reshore & Development) Sara Eastman, AIA, NCARB (Director, Science & Technology, EwingCole) Jeff Wells (Vice President, Strategy and Innovation, VaLogic, LLC.)

2:00 –3:40 pm

Session 6. Grant for US Business: Small Business Innovation Research (SBIR)

Moderator: Cheol Lee, Ph.D.

Overview of NIH SBIR
Meena U. Rajagopal, Ph.D. (Program Officer, Office of Strategic Alliances, NCATS, NIH)

NCI specific SBIR
Jonathan Franca-Koh, Ph.D., MBA (Program Director and Team Leader, NCI SBIR Development Center, NIH)

NHLBI specific SBIR
Stephanie Davis, Ph.D. (Small Business Program Manager, NHLBI, NIH)

Review process and point
Allen Richon, Ph.D. (Scientific Review Officer and SBIR/STTR Review Coordinator, CSR, NIH)

3:40 –4:00 pm

Coffee break

4:00 – 5:30 pm

Session 7. Digital Health

Moderator: Hyun Jong Kim, MBA

2023 Digital Healthcare Trend
Hyun Jong Kim (CEO, Flann)

Evolution of PCR - Concept of Digital PCR and Its Application
Joshua Han (OPTOLANE)

FDA's Evolving Policy Framework for Digital Health Products
Sung Park (FDA lawyer, Reed Smith)

3:30 – 5:30 pm

Career Development /Job fair

5:30 – 6:50

KPBMA/KHIDI Special Session

Moderator: Mark Hwang, Ph.D.

Greeting
Hee-Mok Won, Ph.D. (Chairman, KPBMA)

Regenerative medicine cellular therapy regulation and research
Kyung Eun Sung, Ph.D. (Senior Investigator, CBER, FDA)

Real-World Data and Real-World Evidence in Drug Development: The opportunities and challenges
Joo-Yeon Lee, Ph.D. (Senior Statistical Reviewer, CDER, FDA)

NIH Grants and Funding Mechanisms
Young S. Oh, Ph.D. (Deputy Branch Chief, NHLBI, NIH)

Q&A

7:00 – 9:00 pm

Dinner/Networking

9:00 –9:10 pm

Closing Remarks

Soonmahn Park Ph.D. (Chief representative, KHIDI USA)

SPEAKERS

Opening Remark

Jimmy Rhee
Special Secretary,
The Governor's Office of Maryland
Small, Minority & Women Business Affairs

Jimmy's public service includes extensive international trade/investment and economic development activities with direct nexus to job creation as Cabinet Secretary for Maryland Governor, and Assistant Secretary of Commerce and Trade for Virginia Governor. Jimmy organized and facilitated trade missions which included meetings with top Pacific Asian political and corporate leaders, recruited international conglomerates, fostered various small business growth programs, and implemented the "National Export Initiative and Entrepreneur Program" in conjunction with the White House. Jimmy has direct oversight of the state's socio-economic procurement programs, sets contracting goals, establishes best practices, and monitors their implementation across 70 state agencies including universities, casinos, etc. Jimmy has over 20 years of private sector entrepreneurial experience in enterprise creation, growth and change management with extensive record of directing turn-around situations ranging from manufacturing to software companies, in addition to identifying new strategic opportunities within the context of evolving macro factors (e.g., shifts in geopolitics, technology, monetary policies, etc.) and connecting interdependent factors for economic strength. Jimmy has consulted various Asian conglomerates and investment firms concerning the topography of the U.S. market and government sector, and secured capital infusions for startups and middle market M&A deals in real estate, energy and technology sectors. Jimmy is a highly sought-after speaker at business and community events, and serves as a board member on numerous professional and educational civic organizations such as Harbor Bank, Salinger Business School of Loyola University, George Mason University – Song Do, NE Maryland University Research Park, MHz Networks, Interprise Investment, etc. He is a recipient of numerous awards from professional organizations and industry leaders including the Korean Presidential Medal for Outstanding Korean American. Jimmy earned degrees from Johns Hopkins University (MAS/MBA) and the University of Maryland (BS). Jimmy studied law for two years and holds a professional certificate in sustainable energy from Stanford University Center for Development and is a certified performance improvement coach.

Keynote Presentation I

Moderated by Hae-Young Ahn, Ph.D., RAC

Keynote #1: Adopting Orphan Diseases-It Take a Village

Insook Kim, Ph.D.
Clinical Pharmacology Team Leader, Division of Inflammation and Immune Pharmacology (DIIP), Office of Clinical Pharmacology (OCP), Office of Translational Sciences (OTS), CDER, FDA

Dr. Insook Kim is a clinical pharmacology team leader in the Office of Clinical Pharmacology, FDA. Dr. Kim has 15+ years of experience in regulatory review of INDs, NDAs, and BLAs in the areas of gastroenterology, hepatology, and inborn errors including development programs for pediatric and rare diseases. Prior to joining FDA, Dr. Kim conducted postdoctoral research at NCI following a Ph.D. in Pharmaceutics from the University of Michigan. Dr. Kim earned a master's degree in Pharmacy from Seoul National University, and a bachelor's degree in Pharmacy from Ewha Womens University.

Abstract: There are about 7,000 known rare diseases and collectively, about 1 in 10 people (or 30 million people) in the U.S. have a rare disease 1 . The Orphan Drug Act enacted in 1983 to incentivize the development of drugs for rare diseases played an important role to promote drug development for rare diseases and resulted in a significant number of drug approval. Despite the progress, more than 90% of rare diseases are still without approved treatments and drug development for rare diseases remains challenging. The speaker will share the regulatory experiences and discuss the considerations for drug development for rare diseases.

Keynote #2: Key IND-Enabling Nonclinical Studies for Rare Diseases: A Regulatory Perspective

Yangmee Shin, Ph.D.
Pharmacologist, US FDA

Dr. Shin received her undergraduate degree and Master of Science degree in College of Pharmacy from Sung Kyun Kwan University in Korea. During the Master course in Sung Kyun Kwan University, she worked as a research assistant at the Natural Products Research Institute, Seoul National University, studying coumarins on drug metabolism. She then received her Doctor of Philosophy degree in Pharmacology from the Ohio State University, College of Pharmacy. During the graduate course, Dr. Shin conducted researches on the pharmacological characterization of thromboxane and prostaglandin receptor antagonists. Following her PhD. degree, Dr. Shin completed Visiting Fellowship and Intramural Research Training Award Fellowship from the National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health. Her main research projects involved signal transduction and molecular mechanism of natural products. She subsequently worked in the Laboratory of Molecular Neurochemistry at the Georgetown University Medical Center, focusing on the expression and function of dopamine receptors and nitric oxide synthases in peripheral tissues. Dr. Shin joined the Division of Bone, Reproductive, and Urologic Products, US Food and Drug Administration, and is currently Senior Pharmacologist in the Division of Pharmacology/Toxicology for Rare Diseases, Pediatrics, Urologic and Reproductive Medicine.

Abstract: Orphan drug development is a unique process with some incentives to pharmaceutical companies. Although the drug approval process remains the same for orphan drugs, sponsors of an orphan drug are eligible for submitting expedited approval processes such as the Fast Track, Breakthrough Therapy, Priority Review designations, and the Accelerated Approval pathway in addition to other benefits. To file a new orphan drug application, certain nonclinical studies are required to support the safety and efficacy of clinical trials. The nonclinical program to support first-in-human clinical trials to approval of an orphan drug should aim the overall clinical risk vs benefit assessment for the given product. The amounts of nonclinical data are determined by the type of drug, clinical indication/population, rate of disease progression, proposed clinical trial, and existing nonclinical or clinical experience. I will discuss key nonclinical studies to support the rare disease drug development and approval process based on available guidances from a regulatory perspective.

Session I. Company Presentation

Moderated by Eunkyung An, Ph.D.

Proteomics in Oncology Clinical Guidance

Sheeno Thyparambil, Ph.D.
Sr. Director R&D, mProbe, Inc.

Dr. Sheeno Thyparambil is a Senior Director (R&D) of mProbe Precision Oncology division. He earned his Ph.D in Biochemistry and Molecular Biology from a joint program with FDA and UAMS. He has deep experience (12+ years) and background in developing and deploying clinical diagnostics products. He is the co-inventor on 29 US issued patents surrounding the use of mass spectrometry for the development of clinical assays. His expertise lies in merging molecular oncology, and multi-omic analysis. He is the site-head for mProbe Rockville unit (CLIA certified/CAP accredited laboratory) where he manages a team of scientists, medical directors and Clinical and R&D staff that is responsible for delivering the clinical report to the oncologists for informed decision making.

Abstract: Majority of molecularly targeted therapies are directed towards the proteins; hence it is crucial to quantify proteins for personalized oncology decisions. Our targeted proteomics approach, which is run in a CLIA certified, CAP accredited laboratory has quantified from thousands of patients from 2-3 sections of FFPE samples. These include biomarkers (sensitivity or resistance) for clinical guidance of the use of antibody-drug conjugate (ADC), chemotherapy, immunotherapy and targeted therapy. Biomarkers for chemotherapy include ERCC1, TUBB3, TOPO1, TOPO2A, hENT1 etc. Targeted/IO therapy biomarkers include EGFR, HER2, HER3, cMET, Trop2, PD-L1 etc. We will present clinical validation data from retrospective clinical trials and also results from recent prospective clinical trials. Additionally, case reports of where proteomics was used for clinical guidance will also be presented.

Empowering Microbiome innovation and discovery – Take your research to the next level

Nur A. Hasan, Ph.D., MBA
President and CEO, EzBiome Inc., USA.

Dr. Nur A Hasan is a molecular microbiologist with subject matter expertise in microbial genomics, microbiome, bioinformatics, and molecular ecology. Dr. Hasan received Ph.D. in Genomics and M.B.A in Marketing. Before joining EzBiome, Dr. Hasan was the Chief Scientific Officer at CosmosID Inc, and an Adjunct Professor at the Center for Bioinformatics and Computational Biology at the University of Maryland College Park. Dr. Hasan has professionally served on various prestigious advisory committees (i.e., WHO Expert Panel, ASM NGS Coalition, etc.) and served on the editorial board of multiple prestigious scientific journals.

Abstract: EzBiome is a microbiome company specializing in precision taxonomy, curated databases, and curing-edge genomic intelligence. Our mission is to elevate and transform microbiome discovery aid in developing the next generation of biopharmaceuticals for microbiomerelated diseases. We use precision taxonomy and the world's largest curated reference databases to build class-leading bioinformatics, allowing for accelerated discovery and development of promising candidates for treating diseases.

Redefining Cancer Therapies

Yong H. Park, MD.
CEO, MedGene Therapeutics

Dr. Park, CEO at MEDGENE, has focused on developing clinical applications of autologous cell therapy (Stem cells, Cytotoxic T cells) for over 20 years. Previously he had been in the clinical field for more than 20 years as a Board-certified Orthopedic Surgeon in South Korea. He is currently a member of the American Academy of Orthopedic Surgeons, Korean Orthopedic Association, ASCO, and Korean Bone and Joint Tumor Society.

Abstract: MedGene Therapeutics is a Cell Therapy (T cell reprogramming) company based in Maryland, USA. T-cell exhaustion problems during the CAR-T/ TCR/ TIL/ CPI therapy will eventually be prevented by our RIV-8 technology. Even the terminally exhausted T cells could be reinvigorated by our RIV-8 platform (GAME CHANGER!!). And with another platform, PBL-T (Neo Ag targeting T cells from peripheral blood), we are focused on developing the product for the treatment of solid tumors -- rare, orphan, high unmet need.

Keynote Presentation II

Moderated by Byung Ha Lee, Ph.D.

Keynote: Translation of Innovation into Medicine: MyoKardia Story

June H. Lee, MD FACCP
Venture Partner, 5AM Ventures
Board Director, Cincor Pharmaceuticals, Teneya Therapeutics, GenEdit and Eledon Therapeutics
Scientific Advisory Board, Foresite Labs
Adjunct Professor, UCSF School of Medicine

June H. Lee, MD FACCP joined 5AM as a Venture Partner in 2022. Dr. Lee is a physician-scientist with over 20 years in the biotechnology and pharmaceutical industry. Most recently, she was Founder and CEO of Esker Therapeutics. She previously served as Executive Vice President, Chief Development Officer and Chief Operating Officer of MyoKardia where she built and led a world-class development organization that was acquired by Bristol Myers Squibb for $13.1 billion in November 2020. The lead program at MyoKardia, mavacamten, was recently approved by the FDA for use in obstructive hypertrophic cardiomyopathy patients as the first precision therapy in this indication.

Prior to MyoKardia, Dr. Lee was Professor of Medicine at UCSF School of Medicine, where she served as Director of Translational Research and built the Catalyst Program, an internal accelerator for early-stage technologies. As the therapeutic area head at Genentech, Dr. Lee led early clinical development programs in cardiovascular and metabolic diseases, infectious diseases, and respiratory diseases.

Dr. Lee serves on numerous boards in the healthcare industry including the Advisory Board for Johns Hopkins University Center for Therapeutic Translation, the Board of Directors for Tenaya Therapeutics, CinCor Pharma, Eledon Pharmaceuticals Inc. and GenEdit, and is a member of the Scientific Advisory Board for Foresite Labs. She is also Adjunct Professor at UCSF School of Medicine. Dr. Lee received her undergraduate degree in chemistry at the Johns Hopkins University, earned her medical degree at the School of Medicine at University of California, Davis, and completed her clinical training in internal medicine and pulmonary and critical care at UCLA and UCSF. Dr. Lee is based in the San Francisco, CA office.

Session 2. BioTech Support Programs

Moderated by JongJoo Lee, Ph.D.

Government Support Programs in Fairfax County

Christy Youk, BS
International Business Investment Manager, Fairfax County Economic Development Authority

Christy Youk is an International Business Investment Manager at Fairfax County Economic Development Authority, helping Korean technology companies to expand their business in the United States. She provides business consulting, advising Korean companies with market entry readiness, real estate intelligence, communications with media outreach, and connections to local businesses. With her IT Sales background, Christy advises Korean companies on sales and marketing strategy in the US market.

Abstract:

- Why Fairfax County
- Local Incubators
- Tax Incentives for relocation
- Export program
- HR Incentives
- Career Fairs
- Fairfax County Economic Development Authority Services

Accelerating Drug Discovery to Commercialization from Korea to the U.S.

Ernesto Chanona, Ph.D.
Director, Business Development & Government Affairs, CSSi LifeSciences; Adjunct Professor, Johns Hopkins University

Ernesto Chanona, PhD, currently leads the business development and government affairs division of CSSi LifeSciences; a global biotechnology consultancy and CRO. He works with emerging Korean pharmaceutical and medical device companies to support their US market entry through investor relations, FDA approval, and strategic partnerships. He was invited by KOTRA to speak at the Global Bio & Pharma Plaza 2022 and will return to Seoul from Nov. 28th through Dec. 3rd to speak at the Bio Incheon Global Confex. On his spare time, Ernesto sits on the Board of the American Red Cross and serves as an Adjunct Professor at the Johns Hopkins University.

Abstract: In 2020, Korean pharmaceutical exports to Germany ($19.1B USD) were greater than twice the amount to the United States ($8.8B USD), even though the US poses a greater market opportunity for Korean companies. One of the main drivers of this disparity is the perception of the regulatory approval process posed by the US FDA and the dearth of Korea-based support for US FDA applications. In addition, emerging companies often struggle to understand that approaching the regulatory audience is unlike communicating with other stakeholders like academic collaborators, investors, and strategic partners. Therefore, the development of a regulatory thesis is a necessary, strategic method to communicate effectively with the US FDA, ensuring a smooth and untroubled journey to US market entry.

Session 3. KHIDI USA K-Blockbuster

Moderated by Youngmi Ji, Ph.D.

K-Blockbuster Project

Soonmahn Park Ph.D.
Chief representative, KHIDI USA

Dr. Soon-Man Park has been working as a head of the US branch of the Korea Health Industry Development Institute since March 2021 and he is currently playing a role in supporting the advancement of Korean health industry into the American market. When he was working in the headquarters in Korea, he mainly planned and supervised the medical device industry policy, institution research, and business support business. He got his PhD in Bio-medical Engineering from Yonsei University and worked as a policy advisor at the Ministry of Health and Welfare and the Ministry of Food and Drug Safety.

Abstract: KHIDI USA is working on the project called "K-Blockbuster Support for American Advancement", which helps Korean pharmaceutical and bio companies enter into the United States smoothly. Also we are in progress with the following plans so that Korean new drugs can become blockbuster products in the global market such as 1) Mentoring with local professional consulting companies, 2) networking through seminars or technical forums, and 3) Providing information about the US market trend and federal regulations.

Huons Group's successful US Entry

Jay Jaemyung Choi
CEO, Huons USA

Jay Choi is CEO at Huons USA. He received BS from Sogang University's Department of Business Administration; Received Master of Business Administration (MBA) from George Washington University. He served as the Head of the Treasury Department at SK's Hong Kong branch and served as the CEO of a bio-venture ISTECH's U.S.
Later he led overseas operations for Sigma Koki, a global manufacturer of photonics solutions, in Japan and Taiwan and then moved to OptoSigma Corporation. He served as Chief Operating Officer (COO). He joined as Huons USA CEO in 2021.

Abstract: Today marks the 57th year since Huons Group's entry into the pharmaceuticals market. Since then, Huons Group has followed a consistently strong growth trajectory, quickly becoming a leading injectables-specialty company, particularly with the successful launch of dental anesthesia "Lidocaine" in 1979. This product has also received strong local-market reception due to successful localization strategies. Huons entered the KOSDAQ market in 2006, and in 2016, transformed into Huons Global, the holding company. Currently, it is growing as a global healthcare company, conducting business across all major areas of healthcare, including pharmaceuticals, aesthetics, medical devices, and health functional foods. As a group with annual sales of $650M, we have maintained steady annual growth of 10% year-over-year, despite long-term global recessionary forces. Hallmarks of our continued high-growth include world-class ratings of our injectables & eye drop manufacturing lines as well as rapid expansion of influence & adoption in new business fields such as medical devices and health functional foods. Huons USA, a subsidiary of Huons Global that was

only recently established during the COVID-19 Pandemic, saw strong sales & partnership activity from the outset, quickly becoming one of the leading injectable suppliers in the US pharmaceuticals industry, with more growth prospects to come. Since moving to Boston CIC, we have been participating in various bio-industry events & conferences and will continue to focus on networking with key stakeholders in the Academic, Bioventures & Financial industries in order to co-create additional growth opportunities.

A2B2C to Digital therapeutics (DTx)

Sean (Sungjee) Kang, MD, MPH
CEO, WELT corp.

Dr. Sean Kang is CEO of WELT corp., the company spun out from SAMSUNG in 2016. Before Sean found the company, he worked at SAMSUNG electronics for digital healthcare strategy. Sean also served as public health doctor at The Ministry of Health & Welfare to take charge of digital health policy. Sean was nominated on Forbes several times as 2030 Power Leader and Digital Therapy leader.

Abstract: Insomnia Digital Therapeutics is one of the most popular pipelines in DTx. That is why WELT focuses on three keywords to make core competency. Digital biomarker, Decentralized Clinical Trial and Real World Evidence. WELT's insomnia DTx is collecting data through several digital biomarkers. So every process of treatment can be done fully remote. That is DCT. To go to the US market, WELT builds RWE and presents it from academia. RWE for short-term prediction and early alarm will be the key success factor.

Successful Global Partnership with the K-Blockbuster Platform

Jung-hoon Woo, MS
CEO, BW Biomed LLC

Mr. Woo is also CEO of BW Partners in Korea, Co-founder of Bluzen Partners, Advisor of Korea Doctor Preneur, and Board Member of KITEE (Korean-American Innovative Technology Engineers and Entrepreneurs). He was a Head of Seoul Biohub, Director General of KHIDI USA, Director General of KHIDI Singapore, BD Team Leader of Handok Pharma, Vice Chairman of KOCHAM (Korea Chamber of Commerce and Industry in USA). Mr. Woo holds a Master's in Occupational Health and Safety and a bachelor in Chemical Engineering from West Virginia University.

Abstract: Many Korean biopharmaceutical companies are making great efforts to advance into the US, the largest market in the world. However, there are many challenges to overcome to enter the unfamiliar and competitive US market. So, the various partnerships are essential for this long journey from preclinical and clinical trials to registration and commercialization. For these Korean bio-pharma companies, BW Biomed as an official consultant is promoting an effective and successful global partnership in the US by utilizing the K-Blockbuster project carried out by Ministry of Health and Welfare in Korea and KHIDI (Korea Health Industry Development Institute).

Session 4. Panel Discussion: Drug Development Strategy

Moderated by Leo Kim, Ph.D.

Topic: US Healthcare and Pharmaceutical Reimbursement Systems and Impacts on Your Development Strategy

Ted Buckley, Ph.D.
Vice President, Government Affairs, Shionogi

With two decades of experience Ted brings a unique combination of data analytics, strategy insight, and policy prowess to the table. As a Health Care executive, he combines economic analysis with business strategy to drive bottom line impact and growth. He has driven policy changes at both start-ups and established companies that positively impacted both the company and its external stakeholders including patients.

Abstract: US Healthcare System and drug coverage are notorious in their complexity and opacity, and the pricing and reimbursement mechanisms largely remain mysteries to Korean pharmaceutical innovators despite the defining impact on the clinical development strategy and eventual commercial success. In this session, panelists will review the structure and funding of the US insurance systems based on publicly available information (no proprietary or author-specific presentation), pricing and reimbursement mechanisms, including various market access tools such as formulary tiering, rebate, and prior authorization. Panelists will also discuss how drug innovators should incorporate the US market access insights in their drug Target Product Profiles (TPP), and establish evidence-gathering strategy beyond the FDA/EMA approvals for successful market access and financial return on investment, followed by Q& A session.

Sarah Pitluck, MSc
Former Head/VP, Global Pricing & Reimbursement Strategy, Spark Therapeutics, Inc.

Ms. Pitluck has focused the past 20 years of her career on global healthcare access issues including pricing and reimbursement (P&R) strategy, public policy, market access, and patient advocacy for new biotechnology products. Most recently, she was VP and Head of Global P&R at Spark Therapeutics where she priced the first FDA-approved gene therapy for a genetic disease, LUXTURNA®, and led the roll-out of Spark's unique alternate payment options and outcomes-based arrangements. Prior to Spark, she was the Executive Director for Global P&R at Alexion Pharmaceuticals, leading all global reimbursement dossier preparation and negotiations. She also has worked at Genentech and two healthcare consulting companies focusing on policy and reimbursement analyses for a variety of pharmaceutical, biotechnology, and medical device products.

Abstract: US Healthcare System and drug coverage are notorious in their complexity and opacity, and the pricing and reimbursement mechanisms largely remain mysteries to Korean pharmaceutical innovators despite the defining impact on the clinical development strategy and eventual commercial success. In this session, panelists will review the structure and funding of the US insurance systems based on publicly available information (no proprietary or author-specific presentation), pricing and reimbursement mechanisms, including various market access tools such as formulary tiering, rebate, and prior authorization. Panelists will also discuss how drug innovators should incorporate the US market access insights in their drug Target Product Profiles (TPP), and establish evidence-gathering strategy beyond the FDA/EMA approvals for successful market access and financial return on investment, followed by Q& A session.

Moderator: Leo Kim, Ph.D.
Formerly the Head of Business Planning and Operations (BPO), AstraZeneca Hematology R&D

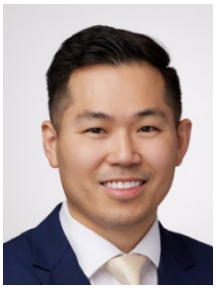
Leo is a seasoned operator with requisite experiences of over 12 years in drug R&D, strategy, corporate operations, healthcare policy and market access. A neuroscientist by training from the University of Pennsylvania, Leo was trained at McKinsey & Company, and worked as a Chief of Staff at Baxter and later Baxalta spin-off. More recently, Leo served as a Director of Value Strategy & Evidence in AstraZeneca to harness the power of clinical outcomes and payer data, and as the Head of Business Planning and Operations with responsibilities to grow and govern the team of +150 innovators. Outside work, Leo served as a Board member for the Night Ministry, a Chicago non-profit organization and was appointed by the Governor to the Virginia Board for the Blind and Vision Impaired, where he oversaw the $6M endowment fund.

Session 5. Panel Discussion: Entering the US Market

Moderated by Jay Park, Ph.D.

Topic #1: Trends in BioPharma Market and Future Perspective

Description: This interactive panel discussion will help the audience understand the current investment market in biopharma in the United States at a view of investment bank, BAIRD. The audience will get insights how to prepare for a capital raising in the global market for the next couple of months or years.



Michael Kim, MBA
Investment Banker, Director, Baird

Michael Kim is a Director and co-leads the biotechnology group within Baird's Global Investment Banking Group. During his investment banking career, Michael has completed over 80 transactions, including public and private equity financings, buyside and sellside M&As, and strategic alternatives. Prior to joining Baird, Michael was a researcher in the Viral Pathogenesis and Evolution Section at NIAID. Michael received his degrees from Cornell University and the University of Virginia.

Topic #2: Beyond location, location, location- Reshoring Best Practices

Description: This interactive panel discussion is ideal for companies seeking Best Practices in establishing new life science or raw material manufacturing facilities in the US. Rapid Reshore & Development, established in response to changes wrought by the pandemic in the fall of 2020, is an alliance of Subject Matter Experts who have joined to offer an alternative to the current facility development model. Our panel of best-in-class professionals is drawn from four separate firms with the common goal of achieving business objectives while optimizing decision making and speed to market. Our delivery approach represents an evolution from transaction-driven service models to a fiduciary focus on the full range of client needs, integrating an inter-disciplinary team customized for each project.

Whether your firm is reshoring manufacturing to the US or establishing US operations for the first time, this topic cuts beyond all the marketing noise and offers real time strategic and tactical know-how.

Methodology: The moderator will guide this panel of experts through the hypothetical establishment of a new US manufacturing facility. Through an interactive discussion modeled after actual Project Working Sessions, the panel will develop "Reverso Biotech's" project charter and establish a roadmap to achieve compliant product production. The moderator will engage the audience to gather input typically provided by supply chain and logistics, environmental health and safety, operational technologies, and other support professionals as stand-ins to help define and guide "Reverso Biotech's" Project.

Panel 1 and Moderator:
Pat Larrabee, MS
President and Founder, FacilityLogix, LLC. and Co-founder, Rapid Reshore & Development

Pat uses her knowledge of science, compliance, and construction to help life science and manufacturing clients align their facility needs directly with their business plan. Pat applies her technical end-user knowledge to facility-related needs throughout the industry. She routinely advises developers, institutions, and companies across the United States and manages their facility expansion and implementation programs. Through her more than 30 years of experience, Pat spearheads accelerated schedules while maintaining control of significant capital expenditures, bringing a SWAT team mentality to the facility development and implementation process.
Pat holds an MS in Biotechnology Management, University of Maryland Global Campus and earned her BA in Biology from the University of Vermont. Pat has held national Board Level positions with Women In Bio and Seeding Labs and devotes much of her time to the mentorship of minorities at the intersection of the life science, commercial real estate, and construction industries. Pull planning will begin with the end in mind, working backwards from the compliant product run date and implementing Lean concepts throughout the manufacturing facility delivery and turnover process.

Panel 2:
Sara Eastman, AIA, NCARB
Director, Science & Technology, EwingCole

Sara is an architect with 20 years of experience in programming, planning, and managing major projects through all phases of design and construction. As a director and laboratory planner in the Science & Technology practice, she is motivated to create beautiful spaces for people who work in the scientific field, inspiring collaboration and creativity for breakthrough advancements in the industry.Sara plans complex projects for clinical and research labs and coordinates with large multifunctional teams across the firm's offices. Her specialty is the detailed planning and programming of specialized laboratory spaces including equipment and casework layouts, utility requirements, and room finishes. Sara holds a Bachelor of Architecture degree from Philadelphia University and is a member of the Clinical Laboratory Management Association and the American Association of Blood Banks.
Sara is a Board Member of the Philadelphia Chapter of Professional Women in Construction.

Panel 3:
Jeff Wells
Vice President, Strategy and Innovation, VaLogic, LLC.

Jeff continues to provide pragmatic operations strategy and compliance advice to clients in addition to playing a key role in driving VaLogic strategy and growth for the past 5 years. Prior to joining VaLogic, Jeff held various quality management positions specializing in building and running quality systems required to support commercialization of new products at small and large firms. Product development experience includes AAV-based gene therapy, bacteriophage, and several vaccines for polio, smallpox, anthrax, and pandemic influenza. In a management consulting capacity, Jeff has advised clients in key focus areas including: design of new facilities/laboratories, optimization of vaccine portfolios, implementing product development tools, optimizing medical device R&D organizations, integrating autonomous large biopharma quality divisions, to remediating deficiencies in quality systems/culture at two separate medical device companies under consent decree with the FDA.
Jeff holds a Master's in Business Administration from the University of Maryland and a Bachelor of Science in Biochemistry from Texas Tech University.

Session 6. Grant for US Business: Small Business Innovation Research (SBIR)

Moderated by Cheol Lee, Ph.D.

Overview of NIH SBIR

Meena Rajagopal, Ph.D.
Program Officer, Office of Strategic Alliances, NCATS, NIH

Dr. Meena Rajagopal is a program officer in NCATS' Office of Strategic Alliances, where she manages a portfolio of Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) grants and contracts. In this role, she is involved in SBIR/STTR outreach activities and serves as an alternate member of the NCATS Small Business Programs Management Committee.
Meena is an experienced translational research scientist and has worked in academia and several research institute laboratories in the Washington, D.C., metropolitan area. Before joining NCATS, Meena was a scientist at the NIH Clinical Center and carried out translational proteomics research in partnership with investigators at Tulane University. Prior to working at the Clinical Center, she was a research specialist at Georgetown University, where she coordinated various metabolomics research projects at the metabolomics facility within the Lombardi Comprehensive Cancer Center. Meena received both her Master of Science and doctorate in chemistry from the University of Kentucky and completed her postdoctoral fellowship at the Children's National Medical Center in Washington, D.C.

Abstract: NCATS works to transform the translational science process so that new prevention, detection and treatment technologies can be delivered to patients faster. Through its SBIR and STTR programs, NCATS fosters small business participation in research and development (R&D) as well as private-sector technology commercialization. These programs are engines of innovation, offering grants, contracts and technical assistance to small businesses and research organizations. The webinar will provide an overview about the

Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR) Programs for researchers and entrepreneurs from underrepresented groups. Learn more about non-dilutive Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR) funding and resources to help small businesses advance and commercialize promising technologies. You will learn about tips for submitting a successful application, upcoming funding opportunities and other diverse resources and programs, including the Applicant Assistance Program (AAP), and the Diversity Supplement Program.

NCI specific SBIR

Jonathan Franca-Koh, Ph.D., MBA
Program Director and Team Leader, NCI SBIR Development Center

Dr. Jonathan Franca-Koh is a Team Leader and Program Director at the National Cancer Institute's Small Business Innovation Research (SBIR) Development Center. Jonathan manages SBIR and STTR grants and contracts with a focus on cancer therapeutics and novel tools for research and drug discovery. He provides oversight throughout the award period and mentors small business applicants and awardees in developing their technology goals and commercialization strategy.

Abstract: The Federal Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are a critical source of non-dilutive financing for early-stage companies. The National Cancer Institute's SBIR Development Center provides over $180M in funding to support the development of innovative cancer related technologies from new therapeutics, to health IT, and everything in between. This presentation will cover NCI SBIR and STTR funding opportunities and programs to support innovators working towards the NCI's goal of improving the diagnosis, treatment and prevention of cancer.

NHLBI specific SBIR

Stephanie Davis, Ph.D.
Small Business Program Manager, NHLBI

Stephanie received her B.S. in Biochemistry and Molecular Biology in 2012 from Florida Southern College. She received her M.S. in Medical Sciences (2015) and her Ph.D. in Molecular Pharmacology (2016) from the University of South Florida. Stephanie was a postdoctoral scholar at the University of Kentucky in the Department of Neurology. In addition to her postdoctoral appointment, she also interned part-time with the UK Office of Technology Commercialization from January to July 2019. Before joining the Innovation Office, Stephanie was selected for the 2019-2020 Executive Branch AAAS Science and Technology Policy Fellows Program, where she served as a Program Manager in the National Institute on Aging Office of Small Business Research. Since 2020, she has worked in the National Heart Lung and Blood Institute (NHLBI) Office of Translational Alliances and Coordination (OTAC) where she oversees the $120M+ SBIR/STTR grant programs.

Abstract: The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR), collectively the Small Business Programs, are also known as America's Seed Fund. By setting aside more than $1.2 billion from its Research & Development Funding specifically for our Small Business Programs, the NIH provides support to early stage small businesses throughout the nation. Many companies leverage NIH funding

to attract the partners and investors needed to take an innovation to market. We focus on a variety of high-impact technologies ranging from research tools, diagnostics, digital health, drugs, medical devices, and others. Dr. Stephanie Davis, the Small Business Program Officer at the National Heart Lung and Blood Institute (NHLBI), will provide an overview of funding opportunities and resources that academic innovators may use to bring their heart, lung, blood, and sleep-related technologies from the bench to the bedside.

Review process and point

Allen B. Richon, Ph.D.
Scientific Review Officer and SBIR/STTR Review Coordinator
Center for Scientific Review (CSR), National Institutes of Health

Dr. Allen Richon began his career in drug discovery and development at Ciba-Geigy Pharmaceuticals, where he was a medicinal and computational chemist with research interests in cardiovascular and metabolic diseases. He also led the development of research information systems as a senior manager at Ciba-Geigy and subsequently at Glaxo Pharmaceuticals. Dr. Richon also held the positions of business development officer at MetaPhore Pharmaceuticals and CEO LeadScope, Inc. During his 14-year tenure at CSR, Dr. Richon has organized and managed the review of a wide range of grant mechanisms including SBIR/STTRs, Research Centers, Data Hubs, Shared Instrumentation, International mHealth and other RFAs.

Abstract: Attempting to understand the Small Business Innovative Research (SBIR) review process as a beginner can be a difficult task. It is hard to grasp the steps involved in the review session, as each of the nearly 6,000 applications reviewed each year is different. Knowing where your score came from and what it means can help you build a better revision or future application. This presentation will outline the basic review process and teach you what reviewers look for in an SBIR/STTR application.

Session 7. Digital Health

Moderated by Hyun Jong Kim, MBA

2023 Digital Healthcare Trend

Hyun Jong Kim, MBA
Chief Executive Officer, Flann Corp
President, KAPAL CA
Managing Partner, Parliament Venture Capital I

Kim Hyun Jong is the CEO of Flann, a consulting firm that provides consulting for Korean bio-tech companies to advance into the US healthcare market. Currently as the president of KAPAL CA, and previously as C.E.O of a diagnostic company, Mr. Kim has expanded his healthcare network in the US, and built extensive experience in the US healthcare value chain, business development, investment, and FDA regulations. Through these experiences, he is participating as a committee member of the Korean government bio-investment fund.

Abstract: Over past couple of years we have seen many healthcare industries changes, most often created out of necessity as we struggled to deal with the Covid 19 pandemic. As we move through 2022 and into 2023,

some of these trends will continue for the short term, while others will likely be around for a long while. In the digital healthcare, virtual reality, artificial intelligence, augmented reality, and machine learning are expected to be all healthcare technology trends that are going to play a vital role across the healthcare system in 2023.

Evolution of PCR - Concept of Digital PCR and Its Application

Joshua (Seungok) Han
Team leader / Business Development
OPTOLANE Technologies, Inc.

Joshua (Seungok) Han majored in Genetic engineering, Biological Sciences and Biotechnology at Chonnam National University, Korea. Joshua leads the OPTOLANE's business development, global sales, and marketing with his experience of 14 years for developing opportunities for business growth and optimizing marketing strategies. From immuno-diagnostics to molecular market, Joshua has a comprehensive market experience to implement business plan and establish effective networks.

Abstract: PCR (Polymer Chain Reaction) is leading the growth of the IVD (In Vitro Diagnostic) market with rapid technology innovation. Digital PCR is expected to satisfy new demands such as precision diagnosis in today's changing medical paradigm. Optolane has created highly innovative, commercially available systems offer state-of-art PCR combined with an unparalleled combination of sensitivity, speed, flexibility, simplicity, and highly competitive price. During the presentation, you will have better understanding of our new PCR functions and its advantage when used diverse area, including research, diagnosis, and many other businesses.

FDA's Evolving Regulatory Framework for Digital Health Products

Sung Park
Attorney, Reed Smith LLP

Sung provides enforcement, regulatory, and transactional counsel to FDA-regulated companies in developing, distributing, and marketing FDA-regulated products and in particular, digital health products and solutions. Sung is experienced in designing regulatory routes for drug, medical device, and digital health products; reviewing product promotional materials; assisting with recalls and market withdrawals if needed; and working with FDA district offices and headquarters to minimize potential regulatory risk and to ensure that clients can successfully launch and market their products in the United States. Sung also conducts due diligence and represents the clients' interest from an FDA regulatory perspective during M&A, IPO, and other transactions.

Abstract: FDA's regulation of digital health products is continuously evolving to ensure safe and effective products for patients, healthcare professionals, and caregivers, while fostering an environment that encourages innovation for the industry. FDA recently released final guidance for Clinical Decision Support software, updated a number of other relevant guidance documents relating to digital health, and provided an update regarding its Digital Health Software Precertification Pilot Program. Sung will provide an overview of FDA's current regulatory framework, and discuss what the companies should be thinking about in this constantly changing and evolving environment.

NIH-KSA Session: Career Development

Alice Ku, MS, MBA, PMP
Programming Chair, Interim Chapter Vice Chair, Women In Bio: Capital Region; Associate Director, Global Project and Portfolio Management, AstraZeneca.

Alice has over 10 years of experience in the biotech/pharmaceutical industry, spanning from manufacturing, product development, and drug development. She currently manages late stage oncology projects within AstraZeneca, leading teams through multi-million dollar investment decisions and pivotal data readouts. She joined Women In Bio (WIB) as a volunteer at the local Capital Region chapter and then joined the National team, providing communication leadership to all WIB chapters. She currently serves as the Chapter Programming Chair, where she leads event planning with her team. She is also currently the interim Chapter Vice Chair, providing support across the chapter.

Abstract: With over 14 chapters across North America, the nonprofit Women In Bio (WIB) strives to provide women with the opportunity to develop their leadership skills and explore opportunities that enable women to reach their maximum potential throughout every stage of their careers. From offerings such as dedicated mentorship groups, to personal development sessions, to networking events, the Capital Region chapter of WIB aims to provide a continuity of support for women in the life sciences. Alice will provide an overview of the mission and opportunities offered by the local chapter, as well as share benefits of joining the organization.

KPBMA/KHIDI Special Session

Moderated by Mark Hwang, Ph.D.

Hee-Mok Won, Ph.D.
Chairman, KPBMA
Invited Professor, College of Pharmacy, Seoul National University
Visiting Professor, College of Pharmacy, Yonsei University
CEO, Sharing Campaign Headquarters for Senior Citizen

Dr. Hee-Mok Won has been the Chairman and C.E.O of Korea Pharmaceutical and Bio-Pharma Manufacturers Association since March 2017. Based on his Thorough Knowledge and in-depth experience in the field of health care policy and academia, Dr. Won has been one of the international leaders in the health and pharmaceutical industry whose pivotal role has contributed to the domestic pharmaceutical industry's advancement into the global market. Since 2004, Dr. Won had served for Korean pharmaceutical sphere beginning as Chairman of the Korean Pharmaceutical Association. Between 2008 and 2012, Dr. Won served as a member of the 18th National Assembly. During his term in the National Assembly, Dr. Won proposed and passed the “Special Act on Fostering and Support of Pharmaceutical Industry” in order to promote Korean pharmaceutical industry and was given various awards for his excellent service including Moran Medal, Order of Civil Merit. Dr. Won also put focus on writing books in order to share his valuable experiences with Korean people. The titles are: “Every Day I Am Reborn”, “For New and Better Start”.

Regenerative medicine cellular therapy regulation and research

Kyung Eun Sung, Ph.D.
Senior Investigator, Division of Cellular and Gene Therapies, Office of Tissues and Advanced Therapies, Center for Biologics Evaluation and Research, US Food and Drug Administration

Dr. Kyung Sung is a Senior Investigator in the Cellular and Tissue Therapies Branch, Division of Cellular and Gene Therapies in the Office of Tissues and Advanced Therapies, CBER/FDA. Her research focuses on developing new quantitative assays using microphysiological systems to study the impact of interactions between living cells and biomaterials used in the manufacture and characterization of regenerative medicine cellular products. She received her Ph.D. in Chemical Engineering from the University of Michigan, Ann Arbor and did her postdoctoral training at the University of Wisconsin, Madison. She also worked as a patent examiner in Biotechnology at the US Patent and Trademark Office before she joined the FDA in 2015.

Abstract: According to the 21st Century Cures Act, products eligible for Regenerative Medicine Advanced Therapy (RMAT) designation include cellular therapies, therapeutic tissue-engineered products, human cell and tissue products, and any combination products containing such therapies or products. Due to their ability to undergo lineage-specific differentiation, Multipotent Stromal Cells (MSCs) and Induced Pluripotent Stem Cells (iPSCs) are popular sources for producing RMAT products. However, there is a lack of reliable and consistent markers that can predict the safety and efficacy of such cell-based products for their successful clinical translation. This presentation will provide an overview of regenerative medicine cellular product regulations as well as current challenges in evaluating the safety and effectiveness of cellular products.

Real-World Data and Real-World Evidence in Drug Development: The opportunities and challenges

Joo-Yeon Lee, PhD
Senior Statistical Reviewer, CDER, FDA

Joo-Yeon Lee, Ph.D is a senior statistician in the Center for Drug Evaluation and Research at the FDA. She has received a B.S in statistics from Ewha Womans University, M.A and Ph.D in Biostatistics from Brown University.
Since joining FDA in 2007, Dr. Lee has been working as a statistical reviewer for new drug applications and post-market drug safety studies. Dr. Lee has been participating in many working groups and guidance publications on real-world data (RWD) and real-world evidence (RWE) at the FDA. In addition, Dr. Lee has been played major role in FDA-led research projects. Dr. Lee has provided short courses on statistical methods for analyses of RWD at numerous places such as DIA/FDA Biostatistics Industry and Regulator Forum and ASA Biopharmaceutical section regulatory-industry statistics workshop. Currently, Dr. Lee has main interest in the causal inference in observational studies, especially methods for sensitivity analysis for unmeasured confounder(s) and is an active member of quantitative bias analysis working group and serves as FDA statistical collaborator of FDA-funded projects that aims to evaluate methods for assessment of potential for bias due to uncontrolled confounding.

Abstract: Real-world data (RWD) and real-world evidence (RWE), which have been increasingly used within the healthcare system for a variety of purposes, previously had limited utility in drug development as data and evidence from traditional randomized trials are deemed to be gold standard to determine the drug efficacy.

However, under the 21st Century Cures Act (Cures Act) signed into law on December 13, 2016, the Food and Drug Administration (FDA) is directed to develop a program to evaluate how RWE can potentially be used to support approval of new indications for approved drugs or to support/satisfy post-approval study requirements. This brings new opportunities to drug developments.
This presentation will start with general overview of Real-World Data and Real-World Evidence in drug development and introduction to observational studies and causal inference. The opportunities and challenges with RWD/RWE will be discussed from multiple aspects including data quality, study design and statistical methods. At the end of presentation, case studies will be presented.

NIH Grants and Funding Mechanisms

Young Suk Oh, PhD
Deputy Branch Chief, Vascular Biology and Hypertension Branch
Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH)

Dr. Oh is Deputy Branch Chief of Vascular Biology and Hypertension Branch in the Division of Cardiovascular Sciences at NHLBI, NIH. Young received his BS from Chung-Ang University, Seoul, Korea; MS from the California State University, East Bay; and PhD in Physiology and Biophysics from the University of Alabama at Birmingham (UAB) in 1992. He finished his postdoctoral training at Yale University. Young was recruited as an Assistant Professor of Medicine at UAB where he held a joint appointment in the Department of Neurobiology. Young joined the NIH in 2002. He has a long relationship with the NIH: from grantee, grant reviewer, intramural scientist, and extramural scientist.

Abstract: The National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services, is the nation's medical research agency - making important discoveries that improve health and save lives. The NIH is the largest funding source for biomedical research in the world with its annual budget of $45 billion in 2022. The NIH is made up of 27 different components called Institutes and Centers, and each has its own specific research agenda, often focusing on particular diseases or body systems. In this talk, I will go over NIH grant administration process and funding mechanisms.

CONFERENCE ORGANIZERS

Byung Ha Lee, Ph.D.
President, KAPAL

SVP & Chief Scientific Officer, R&D, NeoImmuneTech, Inc.
Previously worked as Senior manager, Corporate Development, Genexine, Inc. Worked as IRTA fellow, NIAID, NIH.
Postdoc, The University of Florida College of Dentistry
Ph.D. in Immunology and Microbiology, The University of Florida College of Medicine

Suntae Kim, Ph.D.
Vice President, KAPAL

Director, Connext Co. Ltd.
Previously worked as CDO, MedGene Therapeutics Inc.; Project Manager & Senior Director, KCRN Research; Principal Scientist, G+FLAS Lifesciences; Postdoc & Research Fellow, NCI, NIH. Ph.D. in Biochemistry & Molecular Biology, Environmental Toxicology, Michigan State University

Sang Tae Park, Ph.D.
Executive Director, KAPAL

CEO, Dx&Vx, a KOSDAQ company
Previously worked at COREE, Psomagen, Children's Hospital Boston, Macrogen Clinical Lab, and Axeq Technologies
Postdoc, Harvard Medical School

Eunkyung An, Ph.D.
Executive Director, KAPAL

Extensive experience in clinical proteomics. Previously worked as a manager at mProbe; a senior Scientist at NantOmics; a scientist at Oncoplex Diagnostics; and a Post-doctoral fellow at the NIAID/NIH
Ph.D. in Biochemistry and molecular genetics, The George Washington University

Helena Hyesook Ahn, Ph.D.
Financial Director, KAPAL

Previously worked as Program Specialist and Biologist at NIH/NCCIH and as Project & Regulatory Associate at KCRN Research
Postdoc, Yale University
Ph.D. in Neurobiology, The Catholic University of Korea

Bumrae Cho, J.D./LL.M.
Program Director, KAPAL

Partner, Dentons US LLP. J.D.
LL.M., Franklin Pierce Law Center (University of New Hampshire)
LL.M., Yonsei University, B.S. Yonsei University
Admitted in DC and MA

Youngmi Ji, Ph.D.
Program Director, KAPAL

Functional Genomicist with extensive experience working at NIH research and DOD military research environment over 20 years.
Worked as Assistant Professor and Staff Scientist at the Uniformed Services University of the Health Sciences (USUHS) and Senior Research Fellow at NIAMS/NIH.
Postdoctoral training in functional genomics at NHGRI/NIH.
Ph.D. in Molecular Developmental Biology, Chungnam National University, Korea.

Cheol Lee, Ph.D.
Scientific Director, KAPAL

Scientist, Kelly Government Solutions
Previously worked at Ulsan National Institute of Science and Technology. Postdoc, NICHD, NIH
Ph.D. in Neuroscience, Uniformed Services University

JongJoo Lee, Ph.D.
Scientific Director, KAPAL

Scientist, Kairos Bioconsulting LLC.
Previously worked as Scientist at NCI. Visiting fellow & Research fellow at NIDDK.
Ph.D. in Molecular Biology, Hanyang University, Korea

Juny Kim, MBA
Public Affairs Director, KAPAL

Vice President, CRScube America, Inc
Previously worked as Director, Clinical Research Marketing, Inc
Associate Director, KCRN Research, LLC
Team Leader, Bison Medical co,. Ltd
MBA, Hood College

Seung-Wook Shin, Ph.D.
Public Affairs Director, KAPAL

Senior Scientist, L&J BIO USA, Inc.
Previously worked as a Postdoc at NIDDK, NIH and JSPS fellow at The University of Tokyo.
Ph.D. in Developmental Biology, Kindai University, Japan

Young O (Dennis) Hahm, MPS
BD Director, KAPAL

Principal, KAIROS GFN
Previously worked as Senior Manager, Korea Trade-Investment Promotion Agency (KOTRA) and Korea International Trade Association (KITA)
MPS in Cybersecurity, the George Washington University and B.A. in Economics, University of Maryland College Park

Jihoon Park, Ph.D.
General Director, KAPAL

VP of Finance, Teraimmune, Inc.
Previously worked as a Post-doctoral fellow at the NHLBI/NIH.
Ph.D. in Biochemistry, Chungnam National University, Korea

Han-Sol Park, Ph.D.
General Director, KAPAL

Immune Response Core Manager, Johns Hopkins BloombergSchool of Public Health
Previously worked as a Visiting Fellow at the NIA/NIH.
Ph.D. in Medical Science, Asan Institute for Life Science, Seoul, Korea

SENIOR ADVISORS, KAPAL

Heemin Rhee, Ph.D.
President, Health Research International

Principal Investigator, International Scientific Standard
FDA DMEP/OND/CDER
Visiting Professor, Howard University Medical School
Associate Professor, Oral Robert University Medical School
Ph.D. in Pharmacology, Ohio State University Medical School

Hae-Young Ahn; Ph.D., RAC
CEO & President, AhnBio Consulting, Inc**.**

Former Deputy Director, Division of Clinical Pharmacology, CDER, FDA
29 years of experience in US FDA
Postdoctoral training in pharmaceutics at the University of Michigan
Ph.D. in pharmaceutics from West Virginia University.

Hong-Woon Yang, Ph.D.
Senior Scientist, Sanofi

Over 16 years of experience in small molecule-based drug discovery
Previously worked at Array BioPharma, CoMentis, and GlycoMimetics
Postdoc, Johns Hopkins University
PhD in Chemistry, Texas A&M University

Luke YS Oh, Ph.D.

Samsung Bioepis
Over 14 years of experience in biopharmaceuticals for small molecules and antibodies. Worked as associate director at Questcor Pharma and Mallinckrodt Pharmaceuticals. Spearheaded immunology research group in Human Genome Sciences. Research scientist and council member at Vertex Pharmaceuticals.
Ph.D. in Neuroimmunology at McGill University and postdoc at UCONN.

Jeong Kuen (JK) Song, Ph.D.

Senior Scientist, L&J Biosciences
Postdoc & Research Fellow, NINDS, NIH
Ph.D. in Neuroscience, Vanderbilt University School of Medicine

COMMITTEE OF KAPAL CA

Hyun Jong Kim, MBA
President, KAPAL CA

CEO, Flann Corp, Healthcare Consultant
Managing Partner, Parliament Venture Capital I, NYC
Harvard Medical School GHLP, US
MBA Washington University in St. Louis – Olin, US
B.A. Yonsei University, Korea

Je Min Yoo, Ph.D.
Vice President, KAPAL CA

Chief Technology Officer, BioGraphene, Inc.
Previously worked as Research Assistant, Johns Hopkins Medical Institute
Ph.D. in Chemistry, Seoul National University
B.A. in Chemistry, Johns Hopkins University

Mike Lee, FACHE, NHA, MBA
Executive Director, KAPAL CA

Managing Partner, Culminate Care
Previously worked as COO, 360 Clinic.md.
Fellow of American College of Healthcare Executives
MBA USC Marshall School of Business.

James Y. Lee
Program Director, KAPAL CA

Director of Business Development, Culminate Care
Previously worked as Director of Community Health, 360 Clinic
Manager, Business Development, KHIDI USA
BA, University of California, Berkeley

Jake Hostetler
Community Engagement Director, KAPAL CA

Head of Business Development, BioGraphene, Inc.
Previously worked as Business Development Manager, NETRONIC Software GmbH and Metadium Technology, Inc
B.A. in International Business & Development, Dickinson College

Kyunghyun Huh, Ph.D.
Public Affair Director, KAPAL CA

Product and Platform Leader, Philips, US
Previously worked as Strategy Director, Philips, Netherlands
Management Consultant at IQVIA (Shanghai, China)
Ph.D. in Behavioural Economics from University of Warwick, UK

Yong Seok Choi, Ph.D.
General Director, KAPAL CA

Chief Technology Officer, Graphene Square, Inc.
Ph.D. in Chemistry, Seoul National University

SENIOR ADVISOR, KAPAL CA

Stanford Jhee, Pharm.D.
Corporate Vice President of Scientific Affairs PAREXEL International

Member of the American Society of Clinical Pharmacology
Member of the Japanese Society of Clinical Pharmacology
Doctor of Pharmacy, University of Southern California (USC)
Studied Biological Sciences from the University of California at Irvine(UCI)

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Hee-Mok Won Chairman
Korea Pharmaceutical and
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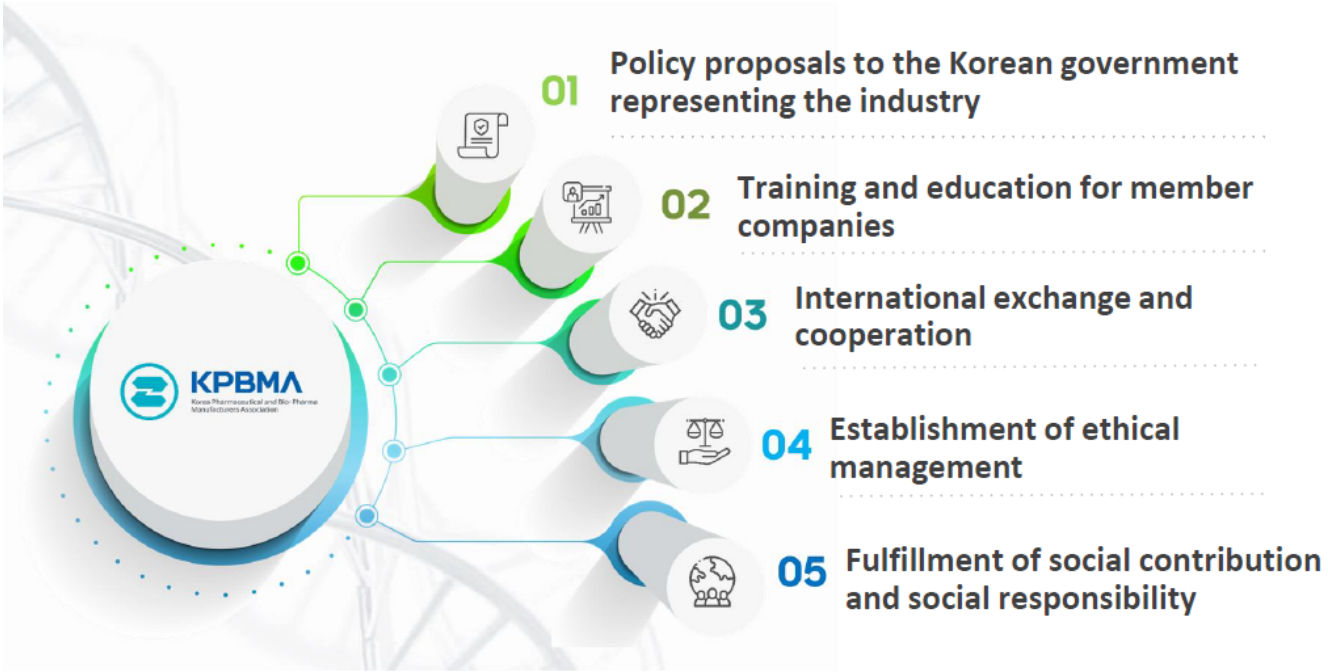
About KPBMA

Korea Pharmaceutical and Bio-Pharma Manufacturers Association(KPBMA) is the largest pharmaceutical industry association in Korea.
It was founded in October 1945, representing Korean pharma industry under the authorization of the MOHW with **260 member companies.**
Under the goal of 'National health promotion through the sound development of the pharmaceutical industry', **KPBMA** plays key roles for the industry advancement such as government relations and policy supporting, training and education for member companies, and global capacity building.
It consists of 10 committees, 11 subcommittees, and 5 special committees to discuss and make decisions on each issue in the pharmaceutical industry.

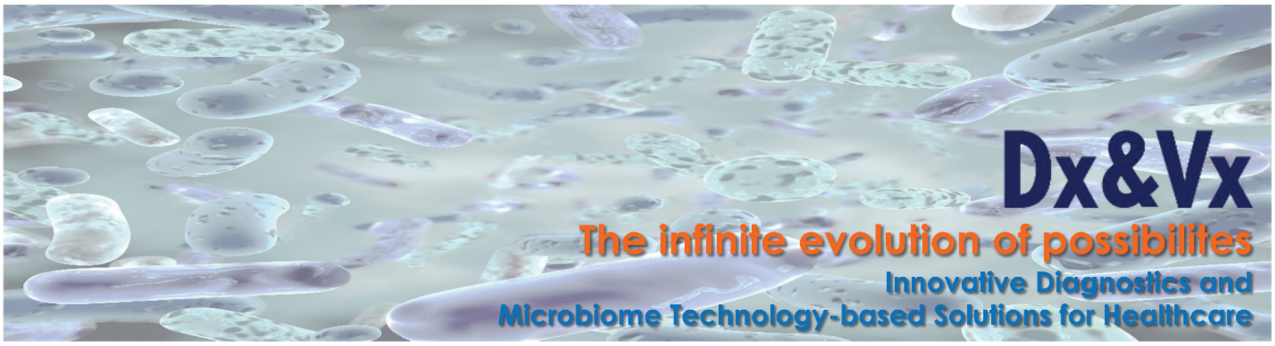
Activities



Kairos

Kairos is an Ancient Greek word meaning the right, critical, or opportune moment.

- **Kairos has completed over $1.6B in deal value.**
- International cooperation in overseas entry of biotech and reinforcement of new pipelines
- Discovery and analysis of domestic and foreign investment destinations



Personalized microbiome therapeutics

Enabling personalized therapeutics throught molecular genetic analysis capacity and acculated microbiota R&D know-how

Customized biomedicine

Providing customized vaccine and antibiotics through OVM-ROP* vaccine platform

Innovative integrated healthcare solutions

Health-centric solutions covering diagnostics, prevention, treatment and care

* **O**xford **V**ac**M**edix(**OVM**) **R**ecombinant **O**verlapping **P**eptide(**ROP**)
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ABOUT US

We believe you can take your business to the next level by expanding your business to the US.

We understand each company has different needs and looks for the better way to success your business in the US healthcare market. Most Korean biotech and pharmaceutical companies eager to enter the US market for the growth of their business. However, most of them struggle how to take the first step into the market.

Our mission is to help you find the right resources you need in the US. Together with you, we will build the success of your business in the US healthcare market.

WHO NEEDS US

Any company struggles with

- ☑ promoting products in the US
- ☑ developing US business strategy and creating roadmap
- ☑ producing pitch deck fit for US investors and US funding procedures
- ☑ approaching FDA resources,

V

CONTACT

FLANN

contact@flann.team

WHAT WE DO

Marketing

Provide our marketing channels to promote your products, technologies, and services

Business Development

Advise business roadmap to achieve your business goal in the US

Pitch Deck & Funding

Produce a professional pitch deck fit for the US investors, and guide fundings and connect investors

FDA Experts & CRO Network

Connect the most suitable FDA experts and CROs which helps you make the right decision for FDA progress

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Book A Time To Find Out More About Our Offerings

EzBiome is a microbiome company specializing in precision taxonomy, curated databases, and curing-edge genomic intelligence. Our mission is to elevate and transform microbiome discovery aid in developing the next generation of biopharmaceuticals for microbiome-related diseases. We use precision taxonomy and the world's largest curated reference databases to build class-leading bioinformatics, allowing for accelerated discovery and development of promising candidates for treating diseases.

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Supported by High-Quality NGS

We plan on expanding our business capabilities from next generation sequencing (NGS) based microbiome genomic analysis to microbial infection diagnosis. Our state-of-the-art NGS bioinformatics (BI) total solution services will get several significant upgrades.

EzBioCloud

- 16S Microbiome
- Shotgun based microbiome
- Functional analysis

TrueBac ID

- Genome based infection diagnosis
- Designed for rapid results

Gut Inside

- Human Gut Microbiome based reporting
- Find your gut type

We offer high-quality sequencing and bioinformatic at an affordable cost, resulting in robust, statistically aware analyses and increasing the likelihood of the desired outcome with more rigor and reliability

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and Enhancing Immunity to Infectious Disease

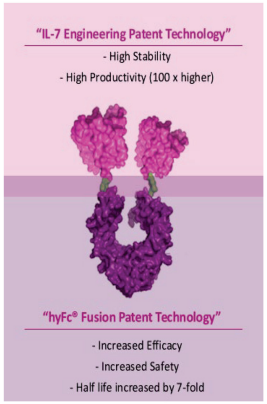
SITC 2022
NOVEMBER 8-12 BOSTON MASSACHUSETTS

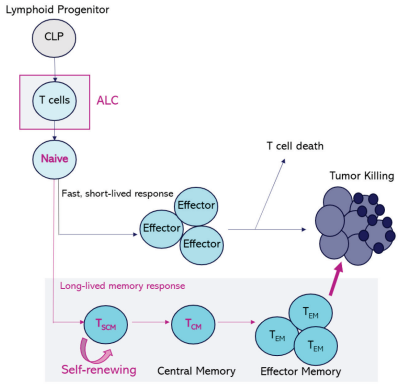
NT-I7 (Efineptakin Alfa)

The only clinical stage, long-acting human IL-7,
a homeostatic cytokine with the unique ability to expand
naïve and antigen-experienced T cells.

Why NT-I7?

- **Powerful T-Cell Amplification**
  - Absolute Lymphocyte Count (ALC) T cells in blood were increased (observed in 100% patients treated: 3x to 30x)
- **Functional Enhancement of T-Cells**
  - **T cells** increase proportionally more than NK cells
  - Less differentiated T cell populations are selectively increased: such as naïve, central memory and stem-like memory T cells
  - **No meaningful changes** were observed in B cells, effector T cells, regulatory T cells.
- **NT-I7 promotes reactivation and migration of T-cells**
  - T cells infiltrated immunologically cold tumors (observed in > 80% patients treated; 50% had > 5x increase)





NI-I7's Addresses Unmet Needs in:

CPI Combinations to Overcome
- \+ Low Number of T Cells (lymphopenic patients)
- \+ Suppressed Function of T cells
- \+ Low Infiltration of Lymphocytes in Tumor (Immunologically Cold Tumors)

CAR-T Combinations
- \+ Enable & Enhance T-cell Production Before CAR-T
- \+ Increase Durability of Response After CAR-T

Chemo/Radiation Combinations
- \+ Overcome Chemo/Radiation-Induced Lymphopenia (Newly Diagnosed GBM (+CCRT))

NT-I7 Advantage

1) Safety, both as mono- & combination therapies, has been confirmed from 600+ patients globally

2) T_{SCM}, which has a strong anti-tumor effect, is selectively and strongly amplified

3) Increase in CD8+ Tumor Infiltrating Lymphocyte (TIL) was clinically observed for multiple cancer types

4) TIL increased proportionally to T_{SCM} (clinically observed)

5) TIL increase led to improved clinical response

SITC Presentation, 2022

Scan Here for Abstracts

On-Going Clinical Trials and Collaborators

Program	Study	Indication	Combination	Preclinical	Phase 1	Phase 2	Phase 3	Collaborator
NT-I7 Combination therapy								
+ Checkpoint Inhibitor	NIT-106	High Risk Skin Cancers Melanoma/MCC/cSCC	TECENTRIQ®		Phase 1b/2a			Roche
	NIT-109	Gastric Gastric, GEJ, EAC	OPDIVO®		Phase 2			Bristol Myers Squibb
	NIT-110	Solid Tumors TNBC, NSCLC, SCLC, PC, MSS-CRC, Ovarian	KEYTRUDA®		Phase 1b/2a			MERCK
	NIT-119	NSCLC 1L	TECENTRIQ®		Phase 2			Roche
	NIT-120	Recurrent GBM	KEYTRUDA®		Phase 2			MAYO CLINIC
+ Chemo/Radio	NIT-104	GBM severe lymphopenia	CCRT[5]		Phase 1/Pilot			
	NIT-107	Newly diagnosed GBM[3]	CCRT[5]		Phase 1/2			Washington University in St. Louis School of Medicine
+ CAR-T	NIT-112	Large B-cell lymphoma (LBCL)	KYMRIAH®		Phase 1b			
+ Vaccine	NIT-105	Vaccine Adjuvant Elderly Cancer Survivors	Vaccine[4]		Phase 1/1b			NIH NATIONAL CANCER INSTITUTE
NT-I7 Mono therapy								
NT-I7 mono	NIT-108	Kaposi Sarcoma			Phase 1			FRED HUTCH
	NIT-113	Progressive Multifocal Leukoencephalopathy (PML) [1]			Pilot			NIH
	NIT-114	Idiopathic CD4 lymphopenia (ICL) [2]			Phase 1/2			NIH
	NIT-115	Squamous cell carcinoma of head and neck (SCCHN)			Phase 1			UCSF
	NIT-116	Covid-19			Phase 1			NIH UNMC
	N/A	Acute Radiation Syndrome		Preclinical				

1. Orphan Drug Designation (US Jun. 2020) 2.Orphan Drug Designation (EU May 2017 US Apr. 2019) 3. Orphan Drug Designation (US Jul. 2022) 4. Td, Polio, Hepatitis A, B 5.Concurrent Chemoradiotherapy

Investigator-initiated trial

For questions about potential partnership opportunities, please contact BD@NeoImmuneTech.com.

Your Genomics Experts

Since 2004, Psomagen (formerly Macrogen USA) has provided superior data quality and next-level technical support to our clients. Our North American researchers are able to complete multiomics projects and get actionable results, all from one service provider.

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Our customers at pharmaceutical, industrial, and academic institutions use Psomagen for reliable, high-quality data. We work hard to ensure your samples are treated with care, and that they produce meaningful results.

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Our team is practically an extension of yours: resourceful, responsive, and your side every step of the way.

High-Quality Data

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