Outsourcing in Clinical Trials & Clinical Trial Supply East Asia

Outsourcing in Clinical Trials Clinical Trial East Asia 2023

Seoul, South Korea, JW Marriot Seoul

5th-6th December 2023

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The leading Outsourcing in Clinical Trials conference in East Asia is returning on 5th-6th December 2023. With a focus on providing delegates with practical take-aways and solutions to their most current operational and outsourcing challenges in clinical trials, this is an event not to be missed.

Focusing on the regional pharmaceutical business in Asia, highlighting the industry's current difficulties as well as its exciting innovations and growth prospects

2023 Speakers

Moon Hwan Kim, Chief Technology Officer, Veraverse
Jaehyun Park, Managing Director, Animuscure
Tina Sun, Study & Site Operations Country Head (Taiwan)- Novartis
Sangho Ma, Chief Development Officer, Bilix
Guoqing Yang, Executive Director, Clinical Quality Assurance,(China)Shanghai Henlius Biotech
Sol Han, Chief Medical Officer, Cyrus Therapeutics
Nari Yun, Executive Director, Clinical Development, GI Innovation
Taegyun Park, Head of R&D, Qratis
Jessica Thongcharen, Director Global Patient Safety, Clinical Operations(Singapore), Takeda
YoungSu Noh, Clinical Science Manager, Hanmi Pharma
Sueun Song, Division Head of Clinical Development, Celltrion
KangPyo Lee, Vice President, Hanul TL
Seoyeon Hyun, Clinical Development Director, ILIAS Biologics
Jungwon Jung, Manufacturing Manager, HK inno-N
DaeMan Moon, Director, Team Leader, Global Clinical Supply Management Team, Celltrion
Juhee JEON, PV Manager, PV Team Leader, HANA pharm
HyeJung Yang, Clinical Project Manager, MedPacto
Yohan Bae, Executive Director, Clinical Development Division, Kangstem Biotech
Eunsun Lee, Director, TiumBio
SoYoung Chun, Medical Director, Trial Informatics
Shin-Il Kim, Chief Scientific Officer, THERABEST
Baek-Jae KIM, Country Manager Korea, IATA
Hyesung Shin, Managing Director, Division Head Clinical Research Development Division, TiumBio
A Young Kim, R&D division Team leader, Jeil pharm
Yooni Kim, Vice President Clinical Services, Novotech
Marine du Jardin, APAC Regional Manager & Partnership Lead, N-SIDE
Amaury Jeandrain, Vice President of Strategy, N-SIDE

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Outsourcing Clinical Trials East Asia

DAY 1 – 5th December 2023

8:00	**Registration and refreshments**
8:50	**Chairperson's opening remarks**
9:00	**KEY NOTE** **Choosing the right CRO: Essential considerations for a successful partnership** • Recognizing common misconceptions when selecting a CRO that may not align with your values and trial requirements • Determining the essential resources and capabilities that the CRO must possess to ensure the success of your trial • Managing that all important budget to avoiding overspending **Sueun Song, Division Head of Clinical Development, Celltrion**
9:30	**Reducing drug waste - how Technology makes clinical supply more efficient** • Drug waste in clinical trials: why is it a big deal? • Identifying the main drivers of waste • How technology enables more accurate and sustainable supply planning, leading to costs and drug waste reduction • Illustration through case studies **Marine du Jardin, APAC Regional Manager & Partnership Lead, N-SIDE** **Amaury Jeandrain, Vice President of Strategy, N-SIDE**
10:00	**Master protocols in biotech: Design and implementation** • Concept of master protocols • FDA perspectives on mater protocols • Operation of complex study design • Examples of mater protocols **Nari Yun, Executive Director, Clinical Development, GI Innovation**
10:30	**The Future of Clinical Trials: Clinical Innovation Solutions Utilizing of Artificial Intelligence (AI)** • The key trends in the clinical trials landscape • How to do CROs use AI in clinical trials • Real-world cases of AI and CRO **Yooni Kim, Vice President Clinical Services, Novotech**
11:00	**Morning refreshments and networking**
	STREAM A: Outsourcing Clinical Trials

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11:30	**The challenges and benefits of Risk-Based Monitoring models in clinical trials** • Understanding the challenges and barriers in implementing risk-based monitoring models in clinical trials • Choosing the correct RBM strategy to apply to your trial to reduce the time to approval for INDs • Discussing the benefits of risk-based monitoring in optimizing resource allocation, such as reducing on-site monitoring visits **Sol Han, Chief Medical Officer, Cyrus Therapeutics**
12:00	**Reserved for the Event Partner**
12:30	**Vendor management: Aligning vendors and sponsors for successful trial delivery** • Addressing the challenges associated with working with multiple vendors instead of a single CRO and offering insights on how to align goals and streamline operations effectively • Emphasizing the importance of clear and consistent communication, as well as fostering strong relationships with vendors and CROs • Exploring the optimal level of oversight and sponsor involvement in the CRO partnership **Eunsun Lee, Director, TiumBio**
13:00	**Lunch and networking**
14:00	**CASE STUDY** **Successful Clinical Trial in Oncology; Dose Optimization in Oncology Drug Development** • Ensuring strict adherence to the inclusion and exclusion criteria is vital to select the appropriate patient population for your oncology trial • Carefully selecting clinically meaningful and relevant endpoints is crucial in oncology trials Compliance with regulatory and ethical considerations in oncology Trials: Upholding Good Clinical Practice (GCP) Guidelines **YoungSu Noh, Clinical Science Manager, Hanmi Pharma**
14:30	**Reserved for the ViroClinics**
15:00	**Development of Clinical Grade iPSC-Derived NK cells for Cancer Immunotherapy** • Utilizing iPSC-derived NK cells as a promising avenue in cancer immunotherapy • Harnessing the potential of iPSC technology for personalized and effective treatments • Offering a versatile and targeted approach to combating various cancer types with enhanced therapeutic efficacy **Shin-Il Kim, Chief Scientific Officer, THERABEST**
15:30	**Afternoon refreshments and networking**

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16:00	**Addressing Management Risks and Challenges in Implementing Decentralized Clinical Trials (DCT) and Digital Tools in Global Clinical Trials** • Introduction of DCT elements and examples of digital tools in global clinical trials • Addressing potential operation and management Risks • **Tina Sun, Study & Site Operations Country Head (Taiwan)- Novartis**
16:30	**KEYNOTE REUNION DEBATE: How did we do?** This is an opportunity to reflect on the advancements, challenges, and new developments in the field of clinical trials. • **The impact of recent social & political events-** How has the industry adapted to ensure continuity and patient safety? What innovative strategies have been implemented, and how have they shaped the future of clinical trials? • **Regulatory landscape-** latest updates and changes in regulations governing clinical trials. How have these changes impacted trial design, conduct, and data reporting? • **Digital transformation-** What are the latest trends in digital solutions, and how are they being integrated into clinical trial operations? **Moon Hwan Kim, Chief Technology Officer, Veraverse** **Sangho Ma, Chief Development Officer, Bilix** **Tina Sun, Study & Site Operations Country Head, Novartis**
17:15	**Chairperson's closing remarks**
END OF DAY 1 AND NETWORKING DRINKS	

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DAY 2 – 6th December 2023

8:15	**Registration and refreshments**
8:50	**Chairperson's opening remarks**
	STREAM A: Outsourcing Clinical Trials

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9:00	**Case Study: Nanomedicine clinical trials conducted by a Korean biotech in Australia** • Introduction to Nanomedicine and its Significance in Clinical Trials • Rationale for Choosing Australia as the Clinical Trial Location • Overcoming Challenges: Logistics, Communication, and Collaboration • Lessons Learned and Recommendations for Future Cross-Border Trials **Sangho Ma, Chief Development Officer, Bilix**
9:30	**Reserved for the Event Partner**
10:00	**Outsourcing of Pharmacovigilance in Korea: An Example and Experience** • Understanding the current status of pharmacovigilance outsourcing trends in the Korean pharmaceutical sector • Detailing the criteria and considerations for selecting the right outsourcing partner for pharmacovigilance • Sharing methodologies to assess and manage potential risks associated with outsourcing **Juhee JEON, PV Manager, PV Team Leader, HANA pharm**
10:30	**Leveraging Real World Evidence/Data for enhanced study design and execution** • Unveiling how RWE can be effectively utilized to identify and locate patients, expediting the recruitment process • Highlighting the significance of RWE in protocol modelling • Exploring competitive intelligence and landscape assessments to identify investigators with the capacity for your study **Taegyun Park, Head of R&D, Qratis**
11:00	**Morning refreshments and networking**
11:30	**Patient Safety and Evaluation in Clinical Operations: Enhancing Safety and Quality in Clinical Research** • Exploring strategies Including Risk Assessment, Quality Management, Adverse Event Reporting, Safety Monitoring, and Patient-Centered Approaches • Aim for Improved Clinical Trial Outcomes and better patient care **Jessica Thongcharen, Director Global Patient Safety, Clinical Operations, Takeda**
12:00	**PANEL DISCUSSION:** **Clinical Trials in Asia: Insights and Perspectives** **'Unlocking efficient strategies to manage multiple countries' regulations for global trials to increase productivity and achieve high quality results from all operation sites** • Opportunities and challenges in conducting clinical trials in Asia- Advantages and considerations for choosing Asian countries as trial sites • Regulatory landscape- Understanding the unique regulatory frameworks and requirements for clinical trials • Collaboration and partnership opportunities- Collaboration models with local research organizations, hospitals, and academic institutions to leverage

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	Moon Hwan Kim, Chief Technology Officer, Veraverse **Jessica Thongcharen, Director Global Patient Safety, Clinical Operations, Takeda** **Guoqing Yang, Executive Director, Clinical Quality Assurance, Shanghai Henlius Biotech**
12:45	**Lunch and networking**
13:45	**Prize Draw** **Join us for a chance to win one of our prizes, including Apple products**
14:00	**Speaker Hosted Roundtables** Interactive roundtable sessions offer a unique opportunity to come together with your peers to share best practice and develop solutions to critical challenges facing the industry as a whole. Hosted by industry experts and each focused on a single issue, roundtables are an exciting, interactive way to build your personal network and learn from the experience and expertise of others. Roundtable session lasts for 45 minutes, and we'll have a 45min wrap up session
	ROUNDTABLE 1: Establishing strategies for vendor management and oversight to strengthen collaboration **Seoyeon Hyun, Clinical Development Director, ILIAS Biologics**
	ROUNDTABLE 2: Navigating global supply chain hurdles when shipping cold chain supplies oversea **Guoqing Yang, Executive Director, Clinical Quality Assurance, Shanghai Henlius Biotech**
	ROUNDTABLE 3: Decentralized clinical trials and technology **Moon Hwan Kim, Chief Technology Officer, Veraverse**
15:30	**Chairperson's closing remarks**
END OF CONFERENCE	

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