Outsourcing in Clinical Trials & Clinical Trial Supply East Asia

# Outsourcing in Clinical Trials & Clinical Supply East Asia 2023

Seoul, South Korea, JW Marriot Seoul

5th-6th December 2023

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*The leading clinical outsourcing 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**
**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**
**Jessica Thongcharen, Director Global Patient Safety, Clinical Operations(Singapore), Takeda**
**YoungSu Noh, Director, Head of Clinical science, 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**
**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**
**JI IN LEE, Director of Clinical Research unit, Miraculus**
**Yooni Kim, Vice President Clinical Services, Novotech**
**Daniela Caiazza, Senior Director Clinical Services and Innovation, Novotech**
**Marine du Jardin, APAC Regional Manager & Partnership Lead, N-SIDE**
**Amaury Jeandrain, Vice President of Strategy, N-SIDE**
**Sean Smith, Biological Threat Exclusion Coordinator (BTEC), U.S. Customs and Border Protection**
**Gina Reneau, Biological Threat Exclusion Coordinator (BTEC), U.S. Customs and Border Protection**
**Marc van Pruijssen, General Manager Clinical Trial Services & Logistic Excellence and Global Head of Logistics, Sample Handling & CTOS, Viroclinics-DDL, a Cerba Research company**
**George Vlachos, Director, Clinical Trial Supply Akesa**
**Shinwook Nam, Senior Associate Director, Clinical Trial Management, Medpace**

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# Outsourcing in Clinical Trials & Clinical Supply East Asia 2023

DAY 1 – 5th December 2023

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

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| 11:30 | **The challenges and benefits of Risk-Based Monitoring models in clinical trials**<br>• Understanding the challenges and barriers in implementing risk-based monitoring models in clinical trials<br>• Choosing the correct RBM strategy to apply to your trial to reduce the time to approval for INDs<br>• Discussing the benefits of risk-based monitoring in optimizing resource allocation, such as reducing on-site monitoring visits<br><br>**Sol Han, Chief Medical Officer, Cyrus Therapeutics** | **Cold chain management and optimal shipping practices**<br>• Exploring how organisations can improve cold chain management, focusing on temperature-sensitive product handling, storage<br>• Providing insights and strategies for effectively managing cold chain operations, such as risk assessment<br>• Discussing the challenges of shipping temperature-sensitive products and outlining best practices<br><br>**KangPyo Lee, Vice President, Hanul TL** |
| 12:00 | **Winning At Your Drug Development Strategy**<br><br>• Current clinical development landscape<br>• 2024 clinical development strategy considerations<br>• Identifying a strategic partner<br><br>**Shinwook Nam, Senior Associate Director, Clinical Trial Management, Medpace** | **Reserved for Akesa**<br><br>**George Vlachos, Director, Clinical Trial Supply Akesa** |
| 12:30 | **Vendor management: Aligning vendors and sponsors for successful trial delivery**<br>• 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<br>• Emphasizing the importance of clear and consistent communication, as well as fostering strong relationships with vendors and CROs<br>• Exploring the optimal level of oversight and sponsor involvement in the CRO partnership<br><br>**Yohan Bae, Executive Director, Clinical Development Division, Kangstem Biotech** | **Clinical supply strategies: tailoring approaches for successful trials**<br>• Addressing the significance of tailoring clinical supply strategies to match the unique requirements of each trial<br>• Examining proactive steps to manage risks, such as regulatory changes, supply chain disruptions, and unexpected patient enrollment<br>• Discussing the ability to adapt supply strategies in response to unforeseen challenges, minimizing disruptions<br><br>**DaeMan Moon, Team Leader Development Supply Chain, Celltrion** |
| 13:00 | **Lunch and networking** | |

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| 14:00 | **CASE STUDY**<br>**Accelerated approval and Dose Optimization in Oncology Drug Development**<br>• Understanding updated US FDA guidance in terms of accelerated approval and dose optimization in oncology drug development<br>• Establishing a strategy for oncology drug development in line with updated guidance from US FDA<br><br>**YoungSu Noh, Director, Head of Clinical science, Hanmi Pharma** | **IATA Temperature Control Regulations (TCR) on Clinical trials supply chain**<br>• Influence of TCR (Time, Temperature, and Condition) on Pharmaceutical Transportation<br>• Effective Application of Time and Temperature Sensitive Labels<br>• Ensuring Compliance with TCR Regulations in Clinical Trials<br><br>**Baek-Jae KIM, Country Manager Korea, IATA** |
| 14:30 | **Logistic excellence as accelerator of clinical trials: an agile approach.**<br>• Centrally orchestrated logistics as a key enabler for the success of clinical trials;<br>• What logistic expertise is required; how to collaborate and create synergies<br>• Upfront quality investments in processes pay off in results<br>• Proven cases<br><br>**Marc van Pruijssen General manager CTS & Logistic Excellence of Viroclinics-DDL, a Cerba Research Company & Senior Vice President Global Logistics and CTOS for Cerba Research** | |
| 15:00 | **Development of Clinical Grade iPSC-Derived NK cells for Cancer Immunotherapy**<br>• Utilizing iPSC-derived NK cells as a promising avenue in cancer immunotherapy<br>• Harnessing the potential of iPSC technology for personalized and effective treatments<br>• Offering a versatile and targeted approach to combating various cancer types with enhanced therapeutic efficacy<br><br>**Shin-Il Kim, Chief Scientific Officer, THERABEST** | **Medical Monitoring in Oncology Adaptive Trials for Cell & Gene Therapy**<br>• Evolution of Medical Monitoring<br>• Clinical Trials for CGT: From Medical Monitors' perspective<br>• Digital Data Platform for Medical Monitoring<br><br>**SoYoung Chun, Medical Director, Trial Informatics** |
| 15:30 | **Afternoon refreshments and networking** | |
| 16:00 | **Addressing Management Risks and Challenges in Implementing Decentralized Clinical Trials (DCT) and Digital Tools in Global Clinical Trials**<br>• Introduction of DCT elements and examples of digital tools in global clinical trials<br>• Addressing potential operation and management Risks<br><br>**Tina Sun, Study & Site Operations Country Head (Taiwan)- Novartis** | **How to manage the Investigational Product in clinical trials**<br>• Points to consider in relation to Investigational Product(including comparator) when conducting clinical trials<br>• Key Strategic Exploration for Efficient Supply and the use of IRT<br>• Discussing effective risk management strategies to anticipate and mitigate potential challenges, ensure uninterrupted supply, and minimize delays |

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| | | **HyeJung Yang, Clinical Project Manager, MedPacto** |
| 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.<br>• **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?<br>• **Regulatory landscape-** latest updates and changes in regulations governing clinical trials. How have these changes impacted trial design, conduct, and data reporting?<br>• **Digital transformation-** What are the latest trends in digital solutions, and how are they being integrated into clinical trial operations?<br>**Moon Hwan Kim, Chief Technology Officer, Veraverse**<br>**HyeJung Yang, Clinical Project Manager, MedPacto**<br>**Tina Sun, Study & Site Operations Country Head, Novartis** | **PANEL DISCUSSION: Mitigating unnecessary delays in clinical supply logistics: Huddle and Solutions**<br>• Strategies to Minimize Delays in Clinical Supply Logistics<br>• Implementing Effective Communication through Huddles<br>• Practical Solutions for Streamlining Supply Chain Processes<br>**Jaehyun Park, Managing Director, Animuscure**<br>**Baek-Jae KIM, Country Manager Korea, IATA**<br>**Sean Smith, Biological Threat Exclusion Coordinator (BTEC), U.S. Customs and Border Protection** |
| 17:15 | **Chairperson's closing remarks** | |

## Outsourcing in Clinical Trials & Clinical Supply East Asia 2023

DAY 2 – 6th December 2023

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| 8:15 | **Registration and refreshments** | |
| 8:50 | **Chairperson's opening remarks** | |
| | **STREAM A: Outsourcing & Clinical Operations** | **STREAM B: Clinical Trial Supply** |

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| 9:00 | **How to navigate sourcing for clinical trials in China**<br>• Are you confused about where to start sourcing in China?<br>• Do you have concerns about quality and transparency when investing into a trial in China?<br>• Have time, language, and cultural differences affected the efficiency of your project?<br>**Guoqing Yang, Executive Director, Clinical Quality Assurance, Shanghai Henlius Biotech** | |
| 9:30 | **Outsourcing of Pharmacovigilance in Korea**<br>• Understanding the current status of pharmacovigilance outsourcing trends in the Korean pharmaceutical sector<br>• Detailing the criteria and considerations for selecting the right outsourcing partner for pharmacovigilance<br>• Sharing methodologies to assess and manage potential risks associated with outsourcing<br>**Juhee JEON, PV Manager, PV Team Leader, HANA pharm** | **Selecting the optimal CMO Partner for product manufacturing: Key considerations and best practices**<br>• Understanding the importance of aligning with a CMO that shares your values and vision to foster a strong partnership<br>• Evaluating the criteria to assess CMO capabilities<br>• Emphasizing the importance of clear communication channels and effective collaboration between your team and the CMO<br>**Jungwon Jung, Quality Director, HK inno-N** |
| 10:00 | **Leveraging Real World Evidence/Data for enhanced study design and execution**<br>• Unveiling how RWE can be effectively utilized to identify and locate patients, expediting the recruitment process<br>• Highlighting the significance of RWE in protocol modelling<br>• Exploring competitive intelligence and landscape assessments to identify investigators with the capacity for your study<br>**JI IN LEE, Director of Clinical Research unit, Miraculus** | **Streamlining the End-to-End pharmaceutical supply Chain: Enhancing efficiency and quality**<br>• Understanding the complexities and challenges of the end-to-end pharmaceutical supply chain, from manufacturing to patient delivery<br>• Addressing regulatory requirements and compliance<br>• How did we implement effective strategies to enhance the end-to-end pharmaceutical supply chain<br>**Hyesung Shin, Managing Director, Division Head Clinical Research Development Division, TiumBio** |
| 10:30 | **Morning refreshments and networking** | |
| 11:00 | **Patient Safety and Evaluation in Clinical Operations: Enhancing Safety and Quality in Clinical Research**<br>• Exploring strategies Including Risk Assessment, Quality Management, Adverse Event Reporting, Safety Monitoring, and Patient-Centered Approaches<br>• Aim for Improved Clinical Trial Outcomes and better patient care | **Explore importing and exporting requirements for biological materials and how preparation is everything in the modern world**<br>• Understanding the requirement and options for declaring biological materials to U.S. Customs and Border Protection (CBP)<br>• Review of key U.S. regulatory agency authorities, such as CDC, FDA, USDA, and CBP |

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| | **Jessica Thongcharen, Director Global Patient Safety, Clinical Operations, Takeda** | • Discovering the latest non-compliant shipment issues for biological materials and pharma products and tips to avoid them<br>• Learn about valuable resources and contacts for assistance<br><br>**Sean Smith, Biological Threat Exclusion Coordinator (BTEC), U.S. Customs and Border Protection**<br>**Gina Reneau, Biological Threat Exclusion Coordinator (BTEC), U.S. Customs and Border Protection** |
| 11:30 | **PANEL DISCUSSION:**<br>**Clinical Trials in Asia: Insights and Perspectives**<br>**'Unlocking efficient strategies to manage multiple countries' regulations for global trials to increase productivity and achieve high quality results from all operation sites**<br>• Opportunities and challenges in conducting clinical trials in Asia- Advantages and considerations for choosing Asian countries as trial sites<br>• Regulatory landscape- Understanding the unique regulatory frameworks and requirements for clinical trials<br>• Collaboration and partnership opportunities- Collaboration models with local research organizations, hospitals, and academic institutions to leverage<br><br>**Moon Hwan Kim, Chief Technology Officer, Veraverse**<br>**Jessica Thongcharen, Director Global Patient Safety, Clinical Operations, Takeda**<br>**Guoqing Yang, Executive Director, Clinical Quality Assurance, Shanghai Henlius Biotech** | **Supply Chain Panel: Ensuring the highest level of collaboration between clinical trial supply and clinical operations**<br>• Ascertaining how clinical supply can get a seat at the table with clinical operations to streamline capabilities<br>• Discovering how teams can collaborate and how technology can enable this<br>• Sourcing raw materials in order to produce products<br>• Overcoming logistical challenges within supply chain<br>• Discussing how to provide products to patient<br><br>**Jaehyun Park, Managing Director,Animuscure**<br>**Jungwon Jung, Quality Director, HK inno-N**<br>**Gina Reneau, Biological Threat Exclusion Coordinator (BTEC), U.S. Customs and Border Protection** |
| 12:15 | **Lunch and networking** | |
| 13:45 | **Prize Draw**<br>**Join us for a chance to win one of our prizes, including Apple products** | |
| 14:00 | **Speaker Hosted Roundtables**<br>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.<br><br>Roundtable session lasts for 45 minutes, and we'll have a 45min wrap up session | |

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| | **ROUNDTABLE 1: Establishing strategies for vendor management and oversight to strengthen collaboration**<br><br>**Seoyeon Hyun, Clinical Development Director, ILIAS Biologics** |
| | **ROUNDTABLE 2: Q&A Session with U.S. Customs and Border Protection – Here to help with any questions you may have about how to import or export biological materials to or from the U.S.**<br><br>**Sean Smith, Biological Threat Exclusion Coordinator (BTEC), U.S. Customs and Border Protection**<br>**Gina Reneau, Biological Threat Exclusion Coordinator (BTEC), U.S. Customs and Border Protection** |
| 15:30 | **Chairperson's closing remarks** |
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