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Veeda engages with life sciences startups for Phase 1 trial solutions

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Offering a great opportunity to life sciences startups with knowledge and understanding of regulatory pathway



Image caption- L-R- Dr Rajiv Bhardwaj, Head – Analytics & Characterization, Veeda Clinical Research (Biopharma division); Rajkumar Agarwal, Chief Business Officer, Veeda Clinical Research; Dr Ramjee Pallela, Chief Operating Officer, Atal Incubation Center - Centre for Cellular and Molecular Biology (AIC – CCMB); Dr Jagannath Kota; Director (Translational Medicine), Novartis Institute of Biomedical Research; Dr Kiran Marthak, Director – Medical & Regulatory Affairs, Veeda Clinical Research; Dr Abhishek Gandhi, AGM – Business Development, Veeda Clinical Research

Veeda Group in collaboration with Atal Incubation Centre – Centre for Cellular and Molecular Biology (AIC – CCMB) recently organised a half-day symposium on Phase 1 trial solutions for emerging life sciences startup companies, at Hyderabad.

The symposium, titled “Integrated Phase I Trial Solutions for Emerging Biopharmaceuticals: Addressing Development Challenges and Accelerating Timelines” aimed to address the challenges and optimise the processes related to the development of New Chemical Entities (NCEs) and Large Molecules.

Covering various aspects within this domain, the symposium featured an illustrious panel of experts from the pharma and biopharma industry, researchers, scientists, and esteemed regulatory experts.

Dr A. Ramkishan, Deputy Drugs Controller (India) at the Ministry of Health and Family Welfare, Government of India was the chief guest at the symposium. Dr A. Ramkishan delivered the talk and a presentation on “Regulatory Guidelines for Drug Discovery & Development”. He emphasised the importance of various laws and regulations pertaining to the life sciences sector. He offered comprehensive understanding of the regulatory landscape governing novel drug development and shared his advice on how startups in the life sciences and healthcare space can collaborate with the office of Directorate General of Health Services (DGHS).

Dr Ramjee Pallela, COO at AIC – CCMB highlighted the importance of new-age research and emphasised on the use of technology to build connects between Industry, Research Institutes and Regulators. In his opening remarks at the Phase 1 symposium,

Further, Dr Madhusudhan Rao, CEO at AIC – CCMB, addressing the life sciences startup companies, reiterated the role of AIC – CCMB and said, “At AIC-CCMB, we endeavor to build an ecosystem for enabling biotechnology innovation. As Indian researchers and innovators begin to expand the boundaries of science, pursuing novel therapies, diagnostics, medical devices and industrial solutions, we ensure that their technologies are translated into sustainable business solutions that reach the citizens.”

Diving into the significance of "Biomarkers in Drug Development," Dr Jagannath Kota, Director, Translational Medicine at Novartis Institute of Biomedical Research delivered an insightful presentation on Biomarkers and explained how these advanced indicators are revolutionising the way the pharma companies assess and develop new treatments. He shared a case study related to oncology research and explained how the findings in Biomarkers were translated in the clinical trials phase.

Followed by this, was a talk and presentation from Dr Suchita Markan, Scientist and Mission In-Charge of India's Medical Device and Diagnostics Mission Secretariat (MDMS) under the Indian Council of Medical Research (ICMR). Dr Suchita extended an invitation to life science startups to collaborate and engage with ICMR and leverage the opportunity to build connection with research and academic institutes.

Highlighting the importance of preclinical aspects of NCEs, Ravi Kumar C, Head – Toxicology at Bioneeds India Pvt. Ltd., shared intriguing and insightful details about preclinical studies, which provides information on safety, efficacy and helps to determine a starting, safe dose for FIM, (FIRST-IN-MAN).

Advanced Analytical Techniques:

Sharing details of "Analytical Methods for Assessing Higher Order Structure in Biosimilars", Dr Rajiv Bhardwaj from Veeda Clinical Research (Biopharma division) delved into innovative methodologies that are driving the development of biosimilar drugs. Highlighting the Higher Order Structure capabilities and expertise at Veeda, Dr Rajiv presented different biopharma solutions for the start-up companies and invited them to collaborate with Veeda for their specific needs and requirements for

biopharma solutions.

The closing session of Phase 1 symposium witnessed the most awaited talk and presentation on Subject Safety in phase 1 trials of NCEs by Dr Kiran Marthak, Director - Medical and Regulatory Affairs, Veeda Clinical Research. Beginning his talk by explaining the regulatory pathway for first-in-human (FIH) trials, Dr Marthak shared case study related to Theralizumab – Mab and explained the entire process starting from enrollment and dosing of patients, designing of trials, right through conducting SAD and MAD studies until the safety considerations for enrolled patients. Highlighting the challenges in phase 1 studies, Dr Marthak cited Veeda's expertise in conducting complex phase 1 studies for reputed clients.

AIC – CCMB offered great support and extended hospitality to representatives of life science startup companies, which included Aasya Healthcare, PathnSitu Biotechnologies, Consytel Lifesciences, Pulse Pharma, AET Labs, Vcult Lifesciences, Abiogenesis Clinpharm, PopVax Private Limited, Cohance Lifesciences and member companies of IKP Knowledge Park.