July 2025 | Issue:07

Veeda™ Lifesciences

THE VEEDA NEWSLETTER

PRESS RELEASE

AI-Enabled Clinical Trials with Querent™ Platform

Veeda™ Lifesciences x MANGO SCIENCES

- AI powered Patient Matching
- Improving Trials Speed
- Driving Operational Efficiency

New Partnership, Broader Horizons for Clinical Research

A key milestone in expanding Veeda's global reach and accelerating its clinical research capabilities across therapeutic areas.

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Inside Veeda Group: July 2025

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Excellence In Everything

From the CEO's DESK

Veeda™ Lifesciences

Building Smarter Trials: Veeda Lifesciences' AI-Driven Collaboration with Mango Sciences

Our journey toward innovation is defined by one constant: purpose. At Veeda Lifesciences, every step we take in modernising clinical research is grounded in the belief that science must serve patients with precision, relevance, and inclusivity. This month, I'm excited to share a meaningful milestone in our strategic collaboration with Mango Sciences, a healthcare AI company headquartered in Boston.

This partnership brings to Veeda the Querent™ platform, an advanced AI solution designed to transform how clinical trials are planned and executed. With this, we are enhancing our ability to identify diverse and representative patient populations, especially in Oncology. More importantly, we are now able to match the right patients to the right trials with greater accuracy, factoring in not only eligibility criteria but also the clinical, geographic, and social relevance of each study. This move reinforces our broader commitment to data-driven trial targeting, an approach we advance as an essential component of bringing agility to clinical trials. It also strengthens our delivery to clients working in the clinical trial space, and aligns well with the experiences and capabilities we are growing through our European operations. Now, with AI at the core of our operations, we're reinforcing the bridge between clinical data and real-world insights across India and Europe.

This investment is part of a broader strategic vision, one that combines clinical excellence with digital transformation. Together with our prior acquisition of Heads and our growing global network, this partnership strengthens Veeda Lifesciences' position as a next-generation CRO. We look forward to deepening our impact and bringing smarter, more inclusive clinical trials to life.

Warm Regards,
Dr. Mahesh Bhalgat
Group CEO & MD, Veeda Lifesciences

Veeda Voice


FEATURES

Regulatory Reforms & Collaborative Models:
Catalysing Indian CROs Growth in Global Clinical Trials

India's clinical research industry is undergoing a significant transformation, propelled by progressive regulatory changes and the adoption of collaborative business strategies. In recent years, regulatory enhancements have improved the efficiency and transparency of clinical trial processes, while increased mergers, acquisitions, and international alliances have broadened the range of services offered by Indian Contract Research Organizations (CROs). These developments have positioned India as a leading destination for global clinical trials, underpinned by operational excellence, cost competitiveness, and a robust regulatory environment. The sector's growth is characterized by a synergy of affordability, regulatory responsiveness, and innovation, establishing Indian CROs as essential partners in global drug development initiatives.

Dr. Mahesh Bhalgat, Group CEO and MD of Veeda Lifesciences emphasizes about India's CROs growth in global clinical trials. He also spoke that Indian CROs are increasingly adopting collaborative business models, forging partnerships with global CROs.

Regulatory Reforms: Building Trust and Efficiency

India's regulatory landscape for clinical research has undergone significant transformation in recent years, creating a highly favourable environment for Contract Research Organizations (CROs):

- **Implementation of NDCT 2019 Rules:** The New Drugs and Clinical Trials (NDCT) Rules, 2019, introduced a transparent and predictable regulatory regime. This has led to expedited approval timelines—30 days for drugs manufactured in India and 90 days for those developed outside the country—making India a more attractive destination for global sponsors.
- **Digitization of Processes:** The digitization of the clinical trial application process has streamlined submissions and improved transparency, reducing administrative bottlenecks and increasing efficiency for both sponsors and CROs.
- **Enhanced Participant Protection:** The regulatory framework now mandates improved compensation for trial participants in the event of death or permanent disability, increasing trust and participation in clinical research.
- **Selective Waivers for Local Trials:** In certain cases, the requirement for local clinical trials has been waived, accelerating the introduction of

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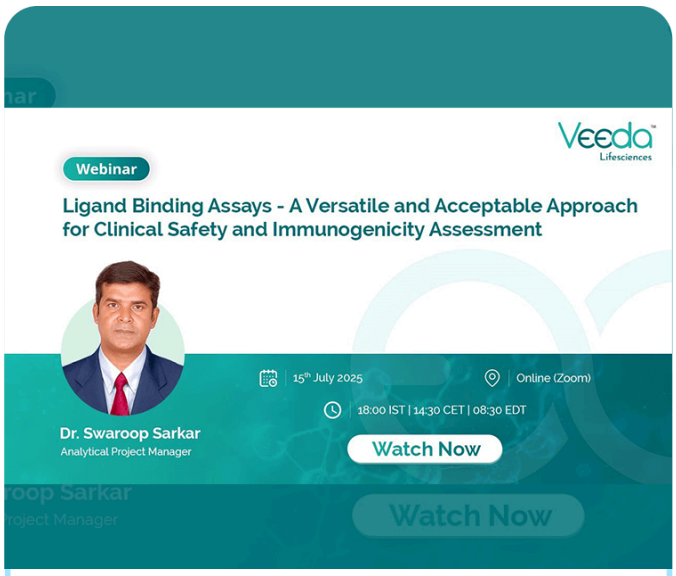
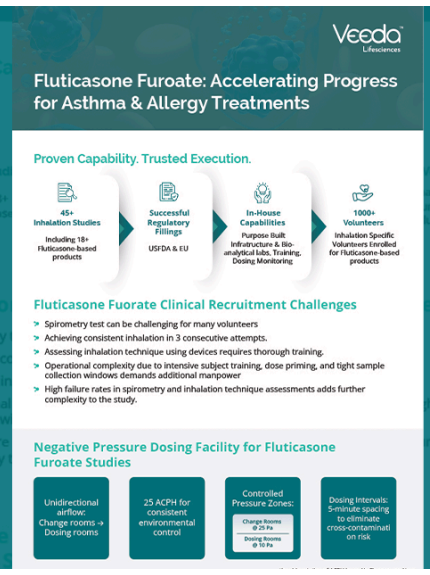
Driving India's Global CRO Growth

Dr. Mahesh Bhalgat shares insights on how regulatory reforms and partnerships are shaping India's role in global clinical trials.



Insights from our Ligand Binding Assay Webinar

Catch up on expert-led discussions by Dr. Swaroop Sarkar covering fundamentals, challenges, and regulatory views shaping ligand binding assay development.



Formulation Insights from Fluticasone Furoate Study

A closer look at how our fluticasone furoate formulation supports large-scale therapeutic consistency.

Understanding Asthma Better

The article highlights real-world asthma care needs and the importance of biosimilar-based solutions.

Industry INSIDER

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US FDA grants priority review and breakthrough status to Imfinzi for early-stage gastric and GEJ cancers.

AstraZeneca's supplemental Biologics License Application (sBLA) for Imfinzi (durvalumab) has been accepted and granted Priority Review in the US for the treatment of patients with resectable,...

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UK MHRA approves Biogen Netherlands' tofersen to treat rare inherited form of motor neurone disease

The Medicines and Healthcare products Regulatory Agency (MHRA) approved tofersen (Qalsody) on 22nd July, 2025 to treat adults with amyotrophic lateral sclerosis (ALS) caused by mutations in the SOD1...

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NLEM-2022 helped patients with annual savings of about Rs 3,788 crore: Ministry

The implementation of prices based on National List of Essential Medicines (NLEM), 2022 has resulted in average price reduction of 17% and estimated annual savings of about Rs 3,788 crore to the patients,...

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Regulation on e-pharmacies yet to see the light of day

Despite draft rules for a comprehensive regulation for online sales of medicines released almost seven years ago, and necessary provisions incorporated in the proposed new Drugs, Medical Devices and Cosmetics...

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Pharmacoeconomics & Real-World Evidence take centrestage in India's regulatory decision-making

India is undergoing a significant transformation, with pharmacoeconomics and real-world evidence (RWE) now taking centrestage in regulatory decision-making. India's regulatory authority, the Central Drugs...

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Delhi High Court refuses to direct Zydus to disclose manufacturing process of Sigrima

The Delhi High Court has said that it cannot issue direction to Zydus Lifesciences to disclose its manufacturing process of its breast cancer drug Sigrima, as petitioner Swiss multinational firm F...

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Industry INSIDER

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Indian pharma adopts automation and IIoT for real-time quality control, traceability, and compliance

Indian pharma is implementing automation and the Industrial Internet of Things (IIoT) to ensure compliance and consistent product quality. By integrating IIoT sensors and automated systems across manufacturing...

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Indian healthcare leads the charge to bridge innovation-awareness gap as tech takes centre-stage

Indian healthcare is coping with a mismatch between medical advances and public awareness. While the country is progressing in targeted therapies and precision medicine, a significant knowledge and...

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MDC rejects Dr Reddy's application to fix separate price for Omaze ODT

The Multidisciplinary Committee (MDC) of Experts, which advices the National Pharmaceutical Pricing Authority (NPPA) in drug pricing in the country, has rejected application of Dr Reddy's Laboratories...

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US FDA delays review of Bayer's NDA for elinzanetant for menopause-related VMS.

Bayer announced that the US Food and Drug Administration (FDA) has notified the company that it has extended the review period for the New Drug Application (NDA) for elinzanetant, the first neurokinin 1 and...

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Opus Genetics and Global RDH12 Alliance partner to advance gene therapy for childhood blindness.

Opus Genetics, Inc., a clinical-stage biopharmaceutical company, announced a strategic partnership with the Global RDH12 Alliance (the Alliance) to advance Opus' gene therapy programme for patients with vision loss due...

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DCGI asks states to monitor NDMA impurity level in ranitidine to monitor and reduce shelf life

The Drugs Controller General (India) has requested the drug controllers of all States and Union Territories (UTs) to direct the manufacturers under its jurisdiction to monitor the N-nitrosodimethylamine (NDMA) impurity...

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Employee SPOTLIGHT

Veeda™ Lifesciences

Veeda at Industry Connect: Bengaluru

On 4 July at CPHI & PMEC India 2025, Dr. Sanjib Banerjee, COO (Biopharma), represented Veeda Lifesciences on a panel discussing R&D, and AI-based optimization in pharma.

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Team Engagement at Vedant Facility

Dr. Mahesh Bhalgat's visit to Veeda's Ahmedabad site fostered conversations with clinical and bioanalytical teams on research focus and collaboration.

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Regulatory AFFAIRS

Veeda™ Lifesciences

Liraglutide Approval: Transformative Impact on Biosimilar Trials

CDSCO approval for Liraglutide in June 2025 marks a watershed moment for Veeda Lifesciences. This approval, granted under the newly formulated 101 route that recognizes approvals from established regulatory authorities, represents the first vertically integrated GLP-1 therapy clearance in India for a market exceeding 77 million diabetes patients.

For Veeda Lifesciences, this approval validates the commercial viability of complex biosimilar and generic molecule development in India. Veeda's established expertise in biosimilar clinical trials, demonstrated through successful studies of molecules like ADL-018 (XOLAIR) and comprehensive PK/PD profiling capabilities, positions the company to capitalize on the growing demand for GLP-1 and other complex therapeutic trials. The approval signals that CDSCO is increasingly receptive to sophisticated biosimilar applications, creating expanded opportunities for Veeda's analytical sciences division and clinical bioanalysis services.

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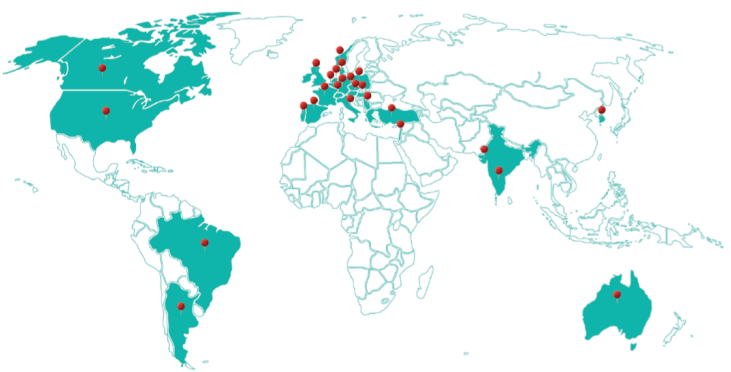

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