# Webinar to showcase how an integrative and holistic approach benefits model-informed drug development (MIDD) outcomes

*Associate Director, Guidance and Scientific Policy at the Office of Clinical Pharmacology, OTS/CDER/OMTP/USFDA, discusses the beneficial outcomes of MIDD*


Rosa & Co. - Drug Development Advisors

SAN CARLOS, CA, US, February 12, 2020 /EINPresswire.com/ -- Today, Rosa & Co. LLC announced a webinar entitled Mainstreaming MIDD: A Holistic and Integrative Approach, to be presented on February 19th by Rajanikanth (Raj) Madabushi, Ph.D. - Team Lead, Guidance and Policy & CDER Point-of-Contact for the MIDD paired Meeting Pilot Program, Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research, USFDA.

"Over the last few decades, it has become clear that MIDD is indispensable for efficient and effective drug development as well as regulatory evaluation of small molecule drugs and biological products," stated the Associate Director. "MIDD provides powerful tools to address a variety of drug development and regulatory questions. The regulatory applications of MIDD can be broadly classified into four categories: dose optimization, supportive evidence for efficacy, clinical trial design, and informing policy."

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> *Dr. Raj Madabushi, FDA*

"As a leading organization in the modeling and simulation space, Rosa is thrilled to host Dr. Madabushi's webinar" said Matt Marano, Chief Commercial Officer at Rosa & Co. "The growth we're seeing in MIDD and its use in addressing regulatory questions are particularly exciting and we look forward to hearing Dr. Madabushi's thoughts and expertise in this area."

Since its inception in 2011, Rosa & Co.'s Worldwide Webinar Series are an invaluable educational resource of how modeling and simulation impact all phases of drug development – with relevant outcomes such as reduced risk, reduced costs, increased confidence, and time and money savings. Over the last eight years, the complimentary monthly webinars have catered to more than 5,000 attendees worldwide, from all drug development disciplines. Speakers have included experts from academia, industry, Rosa client companies, and internal experts.

On February 19th, everyone is welcome to attend the 90th webinar in Rosa's series and hear about how mainstreaming model informed drug development positively impacts patients and society.

Mainstreaming MIDD: A Holistic and Integrative Approach
Rajanikanth Madabushi, PhD
Associate Director, Guidance and Scientific Policy & CDER Point-of-Contact for the MIDD paired Meeting Pilot Program, Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research, USFDA

Model-informed drug development (MIDD) is an approach that involves developing and applying exposure-based, biological and statistical models derived from preclinical and clinical data sources to inform drug development and decision-making. MIDD can be seen as foundational to efficient and effective drug development and regulatory evaluation of small molecule drugs and biological products. There have been many regulatory applications of MIDD to address a variety of drug development and regulatory questions. These applications can be broadly classified into four categories: dose optimization, supportive evidence for efficacy, clinical trial design, and informing policy.

With nearly two decades of experience in demonstrating the relevance and value, MIDD has been recognized as a potential enabler of efficient drug development and decision making. With rapid evolution in new methodologies and the enthusiasm for newer applications, here is arguably a greater appreciation of the benefits and promise of MIDD now more than ever. This is reflected by the inclusion of MIDD-related performance goals in the latest congressionally reauthorized Prescription Drug User Fee Act (PDUFA) VI. Against this backdrop, the key question is how we capitalize on this unique opportunity to mainstream MIDD.

The presentation will provide a brief history of the evolution of MIDD in the Office of Clinical Pharmacology and outline the commitments included in the PDUFA VI. This will be followed by a summary of the various activities under the PDUFA VII MIDD imitative including the early experience and impact. Lastly, the presentation will close out with a call for action aimed at mainstreaming MIDD to achieve consistent and relevant application for patient and societal benefit.

Register to attend the free webinar

About Rosa & Co.
Established in 2002, Rosa & Co. is known worldwide for elucidating the connection between disease mechanisms, therapeutic interventions, and clinical outcomes through its PhysioPD™ Research Platforms. The credible scientific insights and actionable program impact delivered by PhysioPD Research would be difficult or impossible to achieve with any other research approach.

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