

Premier Research and InSilicoTrials Partner to Leverage In Silico Modeling and Simulation and Optimize Regulatory Pathways for Rare Disease Therapies

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MORRISVILLE, N.C. and MILAN and TRIESTE, Italy , March 13, 2023 /PRNewswire/ -- **Premier Research**, whose mission is to help the most innovative biotech and device companies take their best ideas from concept to commercialization, and **InSilicoTrials**, a leader in the use of artificial intelligence (AI) and computational modeling and simulation (CM&S) to accelerate development of new therapies and medical devices, have partnered to create safer, faster, and more efficient pathways to regulatory approval for rare disease treatments.

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Premier Research VP, Statistical Consulting, **Abie Ekangaki**, Ph.D., notes that recent CM&S advances have made possible the full or partial substitution of virtual patients in clinical trials. The FDA supports this as part of the body of evidence required for regulatory submissions in specific circumstances.

As part of the R&D lifecycle, *in silico* trials enable simulated synthetic control or treatment arms, inform strategies for patient enrollment, and more efficiently predict the safety and efficacy of novel drugs and medical devices. Synthetic control arms (SCA) generated using *in silico* CM&S techniques represent a powerful tool for enabling preclinical and clinical research that otherwise might not be feasible, particularly in rare disease research.

Having managed more than 240 rare disease studies across numerous indications in the past five years alone, Premier Research has a long-term commitment to orphan drug development. Partnering with InSilicoTrials, whose *in silico* study design will result in faster submission-ready studies and more effective preclinical review of trial design parameters, is a continuation of Premier Research's ongoing investment in rare disease trials.

"The *in silico* option can transform trials for which it is difficult to recruit or retain patients, such as with rare or imminently life-threatening diseases, with no or inadequate standard of care treatments," Ekangaki said.

"For clinical trials in small patient populations," he added, "*in silico* models that leverage biological, molecular, or genetic data to characterize the disease can generate synthetic control arms, which, together with Premier Research's expertise in preclinical and clinical development, execution, and regulatory aspects of small population trials, can shrink the time it takes to develop effective rare disease therapies."

Ekangaki noted that one huge advantage of *in silico* simulation is the ability to investigate 'what if' scenarios, such as in rare disease, where a larger patient population does not exist.

The partnership between Premier Research and Italy-based InSilicoTrials will emphasize smarter *in silico* study design resulting in more effective pre-clinical review of trial design parameters and faster submission-ready studies.

"Modeling and simulation combined with AI is the most effective way to innovate the R&D process in drug development," InSilicoTrials CEO **Luca Emili** said. "Computational models and AI are true game changers because they enable sponsors to dramatically accelerate the development of new medicinal treatments, improve the safety of medical products, and significantly cut R&D costs."

About Premier Research

Premier Research, a clinical research, product development, and consulting company, is dedicated to helping biotech, specialty pharma, and device innovators transform life-changing ideas and breakthrough science into new medical treatments.

As a global company, Premier Research specializes in the use of innovative technologies for smart study design and trial management to deliver clean, conclusive data to sponsors.

Whether it's developing product lifecycle strategies, reducing clinical development cycle times, securing access to patients, navigating global regulations, maximizing the impact of limited rare disease data, or providing expertise in specific therapeutic areas, Premier Research is committed to helping its customers answer the unmet needs of patients across a broad range of medical conditions. Visit premier-research.com.

About InSilicoTrials

InSilicoTrials is an emerging startup founded by a team of life science, cybersecurity and digital innovation experts, which aims to revolutionize Healthcare through an innovative digital simulation platform. We bring a transition to the future of drug development, with online solutions that can reduce the cost and time of taking a new drug through clinical trials.

At InSilicoTrials, we have developed a vertical software solution combining state-of-the-art AI, simulation tools and patient data utilized to facilitate drug discovery in every step, from compound optimization to drug repurposing. InSilicoTrials built up an ecosystem of more than 70 scientific collaborations, where computational models are developed with internationally recognized universities and research centers, offering access to the highest level of data security.

The *in silico* technology can increase the quality of life of millions of patients by allowing accessible treatments, bringing innovative drugs to the market in a shorter time, together with personalized cures and new solutions for rare diseases. Visit insilicotrials.com.

Tags

Rare Disease, Artificial Intelligence, AI, InSilicoTrials, Computational Modeling, CM&S, Simulation Solutions, Synthetic Control Arms, SCA, Life Sciences, Clinical Trials, Virtual Trials, Medical Products, Drug Development, Biopharmaceutical, Regulatory Approval, FDA, EMA

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