

The future of clinical trials

Conquer the complexity of biology with clinical trial simulations

NOVA's mission is to support better clinical development of new drugs matching them with optimal responding patients. Using the JINKO® platform, clinical trials are simulated with a computational model of the disease of interest and virtual patients of any specific context or geography.

When compared with traditional clinical development, participants in the FDA's Model-Informed Drug Development Pilot Program note significant savings both in time - up to 2 years - as well as in cost -up to \$70 million*.

US FDA selected NOVA for the MIDD Pilot Program in 2019 to present its approach to model design and validation.



Main advantages of *in silico* modeling

01 Accelerate clinical development timelines 02 Solve data & evidence gaps 03 Reduce sample size

04 Increase clinical trials probability of success

05 Address ethical concerns

JINKO® delivers solutions for each critical development painpoint



Tailoring our modeling offer to your needs

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Mechanistic models of disease and virtual patients with JINKO[®] are aimed at helping drug developers generate new insights and manage the complexity of human biology.

Disease models are translated into mathematical representations of physiological knowledge.

Existing trial data can be harmonized and extrapolated. When no data from previous trials are available, trials can be simulated to generate data including fully-functional synthetic control arms with the option to use digital twins.

Superiority of JINKO® over analytical approaches only based on data

Leverage curated knowledge and available data

01 Allow working in data-poor environments

02 Fill data gaps

03 Manage hidden variables

Collaborate in a white box environment

04 Full auditability & traceability

05 Easy-to-use for non-modelers



With more than 160 years of cumulative experience, NOVA has assembled the world's largest biomodeling team over the past 10 years.



Useful resources

Publications

*Perspective on the Benefits Realized From the FDA's MIDD Pilote Programme Verifying and Validating Quantitative Systems Pharmacology and In Silico Models in Drug Development Scientific and regulatory evaluation of mechanistic in silico drug and disease models in drug development Possible Contexts of Use for In Silico trials methodologies

Case studies

Lung Adenocarcinoma - non-small cell lung cancer Myocardial reperfusion injury

Blog posts

ElsaLys

Biotech

<u>Bulding trust in *in silico* modeling</u> <u>Mechanistic models and AI</u> <u>The power of synthetic control arms</u>

They trust us















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