CERTARA

Non-Animal Navigator™

Fact sheet

Expert strategy and AI-enabled biosimulation to reduce, refine, or replace animal studies

Navigate the evolving nonclinical landscape with confidence

Preclinical drug development is shifting rapidly following the FDA's move to phase out animal testing for monoclonal antibodies (mAbs) and other drugs. To stay competitive, companies must adopt more predictive, cost-effective, and accelerated approaches using biosimulation and other new approach methodologies (NAMs). With thousands of mAbs in development, the need to replace animal studies is both a challenge and an opportunity.

Certara's Non-Animal Navigator™ helps drug developers identify and implement optimal NAM strategies through a tailored gap analysis and solution plan, reducing timelines, cutting costs, and ensuring regulatory alignment.

Future-proof drug development with animal-free modeling

Key benefits include:

- **Reduced Animal Use**
  Replace or minimize animal studies with in silico models that meet ethical and regulatory standards.
- **Improved Predictive Accuracy**
  Leverage PBPK modeling to generate more human-relevant insights than traditional preclinical methods.
- **Accelerated Timelines**
  Identify risks earlier and streamline development by eliminating time-consuming animal testing.
- **Regulatory Confidence**
  Deliver robust, mechanistic data to support submissions and align with evolving regulatory expectations.

Core capabilities include:

- **Virtual Trials**
  Simulate drug efficacy and safety in virtual human populations, eliminating the need for animal testing.
- **Mechanistic Modeling**
  Use quantitative systems pharmacology (QSP) to predict human outcomes and understand complex drug behaviors.
- **Regulatory Strategy**
  Design regulatory roadmaps that incorporate non-animal data to meet global submission requirements.
- **Data Integration**
  Aggregate and analyze diverse data sets to build a complete, predictive picture of drug performance.

Maximize impact through our connected solutions

Our Non-Animal Navigator™ Solution seamlessly integrates with our suite of tools and services:

- **Drug Development Strategy and Regulatory Support**
  Leverage expert support and tailored NAM strategies to accelerate drug development, ensure global regulatory alignment, and drive efficient, compliant submissions.
- **Simcyp™ PBPK Simulator**
  Supporting accurate, animal-free predictions of drug behavior, interactions, and dosing to accelerate development and support regulatory decisions
- **Quantitative Systems Pharmacology Models (QSP)**
  Provide mechanistic, human-relevant insights into drug behavior and immune response, reducing reliance on animal studies and supporting confident, data-driven decisions.

Why Choose Certara's Non-Animal Navigator?

2,400+ biopharmaceutical companies and regulatory agencies across 70 countries

>90% of all novel drugs approved by the US FDA since 2014 were supported by Certara services or technology

100+ papers published by Certara's scientists in 2024 alone, with the 12 recognized among the top 2% of cited researchers globally

Connect with our experts today

Embrace a future of ethical, efficient, and effective drug development with Certara's Non-Animal Navigator.

Fran Brown, PhD

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30+ years of experience with strategic and operational drug development from early discovery to filing and post-marketing.

Piet van der Graaf, PharmD, PhD

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30+ years of experience in clinical pharmacology and quantitative systems pharmacology.

Patrick Smith, PharmD

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20+ years of drug development experience, Patrick has worked across all phases of drug development with deep expertise in infectious diseases, oncology, and inflammation.

Hannah Jones, PhD

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20 years of experience in global pharmaceutical organizations, possessing a particularly strong background in PBPK and PKPD modeling.

Have questions? Learn more or contact us here.

About Certara

Certara accelerates medicines using biosimulation software, technology, and services to transform traditional drug discovery and development. Its clients include more than 2,400 biopharmaceutical companies, academic institutions, and regulatory agencies across 70 countries.

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