# Welcome to the 3rd Edition of the

# OSP Community Conference

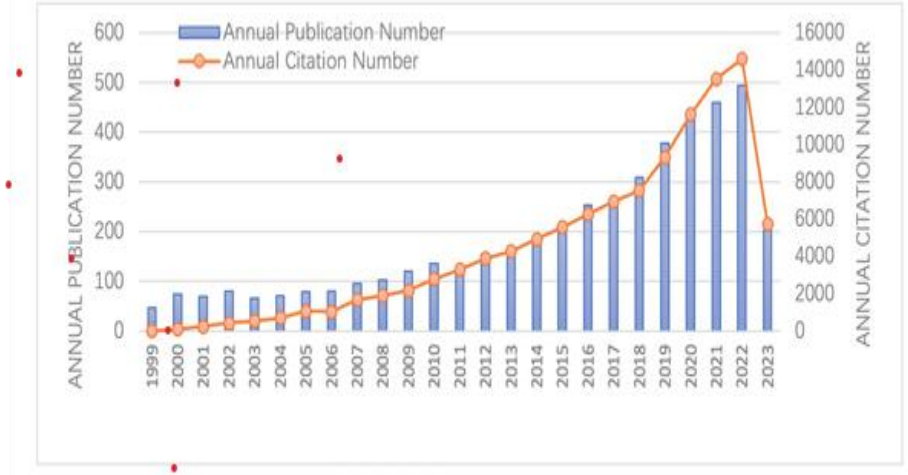
Johnson&Johnson
Innovative Medicine

Claire Mackie

Beerse Campus
September 24-25 2027

# Model Informed Drug Development (MIDD)

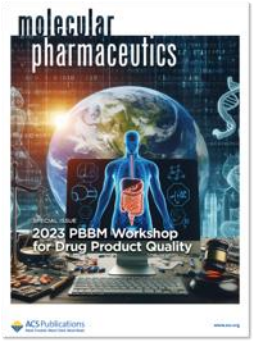
- **Is on the increase ☺**
- Paper published in 2024 (Wang et al., Res vol 41, 609-622) "Research landscape of Physiology Based Pharmacokinetic Model Utilization in Different Fields: A Bibliometric Analysis"
  - 4,649 records identified in the period 1999-2023
  - Largest Number of publications focused across the period of 2018-2023
  - Journal of Drug Metabolism and Disposition published and co-cited the most articles
  - Main topics covered: Drug-Drug Interactions, special populations and new drug development



The annual research outputs.

# 2023 - Today

- **Increased use within Drug Product Quality (PBBM)**
- **2023:**
  - M-CERSI Workshop: Physiology Based Biopharmaceutics Modeling (PBBM): Best Practices for Drug Product Quality, Regulatory and Industry Perspectives: workshop
  - 6 Global Agencies discussing science (ANVISA, MHRA, EMA, FDA, Health Canada, PMDA)




https://pubs.acs.org/toc/mpohbp/22/6

- **2024:**
  - PBBM: Best Scientific Practices to Define Drug Product Performance: Latest Regulatory and Industry Perspectives (APS/MHRA as hosts, EMA & FDA colleagues joining)



https://doi.org/10.3390/pharmaceutics18050566

- **2025:**
  - EMA MIDD Concept Paper for public review,
  - EMA Stakeholder Workshop
  - ANVISA PBBM Draft Guideline for public comment

https://www.ema.europa.eu/en/guideline-assessment-reporting-mechanistic-models-used-context-model-informed-drug-development

https://www.ema.europa.eu/en/events/hma-ema-multi-stakeholder-workshop-reporting-qualification-mechanistic-models-regulatory-assessment

# From 2023 - Today

- **2026**
  - **1st International PBPK conference**

## April 21st to 24th, 2026



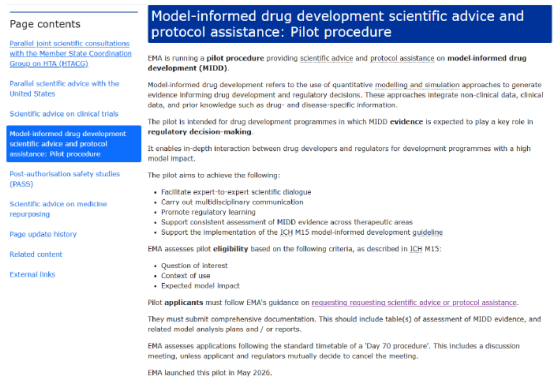
**1st PBPK Conference**

The **1st International PBPK Conference 2026** is set to take place from **April 21st to 24th, 2026**, at the **Novartis Campus in Basel, Switzerland**. This conference is the first global event dedicated to advancing PBPK modeling in pharmaceutical sciences. It aims to create a collaborative environment for scientific exchange, featuring high-impact oral presentations and expert-led panel discussions. The conference will also include pre-conference workshops and a special evening event for attendees to connect within the PBPK community. pbpkconference.org +2

- **EMA MIDD Pilot published**

## MIDD Scientific Advice Pilot

- Scientific advice procedure tailored to development programs with a strong MIDD element
- Launched in May 2026 (Parallel scientific advice and special development aspects or product types | European Medicines Agency (EMA))
- **Why?**
- Calls for expert-to-expert communication in scientific advice procedures (HMA/EMA multi-stakeholder workshop on reporting and qualification of mechanistic models for regulatory assessment | European Medicines Agency (EMA))
- Enables ICH M15 implementation and learnings



Page contents

Parallel joint scientific consultations with the Member State Coordination Group on HTA (HTACG)

Parallel scientific advice with the United States

Scientific advice on clinical trials

Model-informed drug development scientific advice and protocol assistance: Pilot procedure

Post-authorisation safety studies (PASS)

Scientific advice on medicine repurposing

Page update history

Related content

External links

**Model-informed drug development scientific advice and protocol assistance: Pilot procedure**

EMA is running a **pilot procedure** providing scientific advice and protocol assistance on **model-informed drug development (MIDD)**.

Model-informed drug development refers to the use of quantitative modelling and simulation approaches to generate evidence informing drug development and regulatory decisions. These approaches integrate non-clinical data, clinical data, and prior knowledge such as drug- and disease-specific information.

The pilot is intended for drug development programmes in which MIDD **evidence** is expected to play a key role in **regulatory decision-making**.

It enables in-depth interaction between drug developers and regulators for development programmes with a high model impact.

The pilot aims to achieve the following:

- Facilitate expert-to-expert scientific dialogue
- Carry out multidisciplinary communication
- Promote regulatory learning
- Support consistent assessment of MIDD evidence across therapeutic areas
- Support the implementation of the ICH M15 model-informed development guideline

EMA assesses pilot **eligibility** based on the following criteria, as described in ICH M15:

- Question of interest
- Context of use
- Expected model impact

Pilot **applicants** must follow EMA's guidance on requesting requesting scientific advice or protocol assistance.

They must submit comprehensive documentation. This should include table(s) of assessment of MIDD evidence, and related model analysis plans and / or reports.

EMA assesses applications following the standard timetable of a 'Day 70 procedure'. This includes a discussion meeting, unless applicant and regulators mutually decide to cancel the meeting.

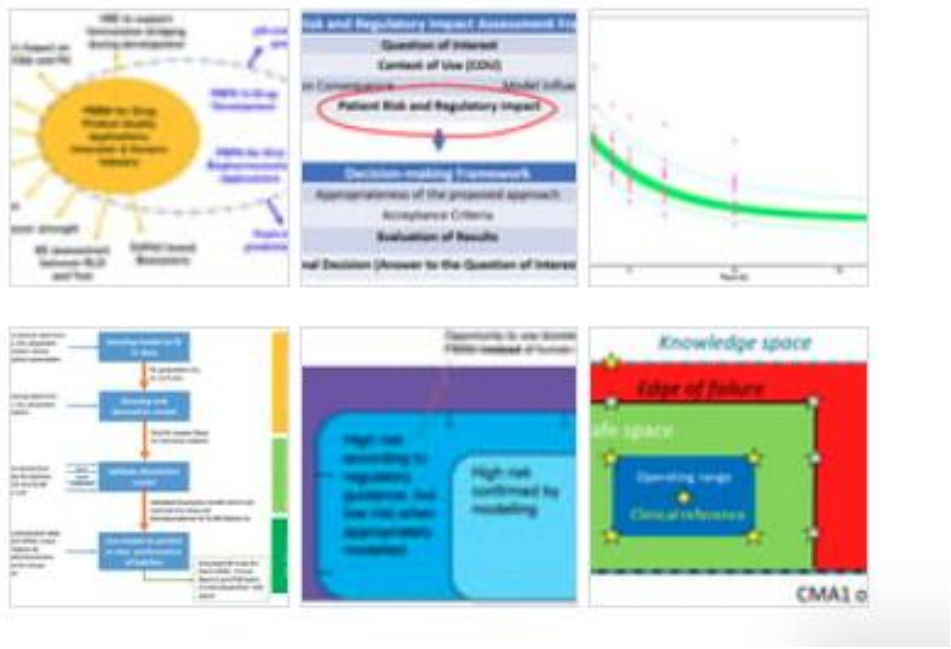
EMA launched this pilot in May 2026.

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EMA

# MIDD…

- **Is here to stay ☺**
  - QSP, PBPK, PBBM, Process Modelling,  we use it every day in furthering our understanding, for internal decision making and interactions with Health Authorities
  - Community conferences are important to keep growing and sharing the combined knowledge
  - OSP 3rd Edition
    - Clinical Application & Development
    - Research & Discovery
    - Submission, Life Cycle & Approval
    - Emerging Areas




Pharmaceutics 2026, 18 (5) 566