EMA
EUROPEAN MEDICINES AGENCY

MIDD Scientific Advice Pilot

16th Industry stakeholder platform on research and development support

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ICH harmonisation for better health

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Human Medicinal Products

ICH M15 Guideline on general principles for model-informed drug development

Step 5

Transmission to CHMP	24 October 2024
Adoption by CHMP	14 November 2024
Release for public consultation	29 November 2024
Deadline for comments	28 February 2025
Final adoption by CHMP	23 January 2026
Date for coming into effect	23 July 2026

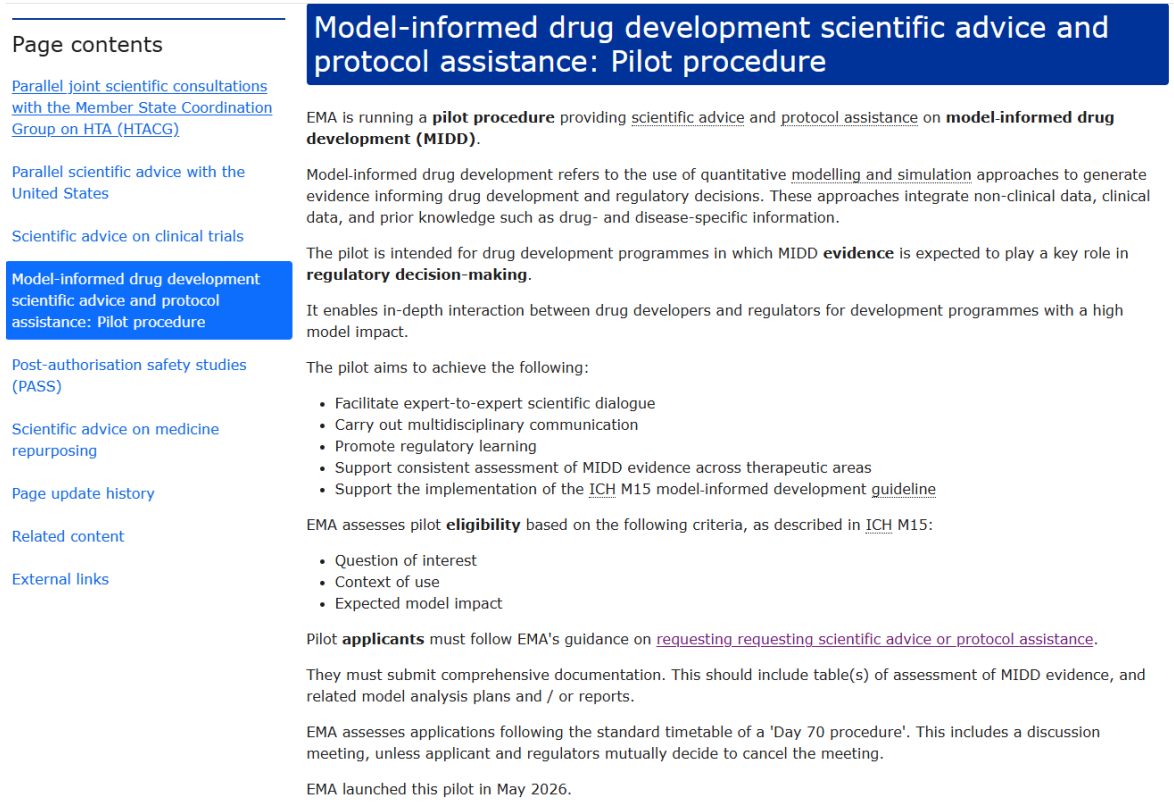
Model Informed Drug Development (MIDD)

MIDD is defined as the use of computational modeling and simulation (M&S) methods that can include and integrate non-clinical data, clinical data, prior information, and knowledge (e.g., drug and disease characteristics) to generate evidence.

The generated MIDD evidence is used to inform drug development and decision-making by drug developers, regulatory authorities, and other stakeholders.

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



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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.

Pilot MIDD Scientific Advice Scope

Development programs with a strong MIDD component, i.e. High Model Impact according to the ICH M15 Guideline. For example, MIDD evidence supporting:

- Extrapolation across populations/indications
- Efficacy and safety of new medicinal products in situations where RCTs are not possible or inconclusive (e.g. single arm trials, underpowered studies)
- SmPC claims regarding special populations and DDIs
- Biowaivers and quality specifications
- Product Lifecycle management decisions
- Faster progression to Phase 3

Pilot MIDD Scientific Advice

Validation

- Eligibility based on assessment of QoI, CoU and Model Impact (ICH M15 GL)
- Submission of complete documentation e.g. table of assessment of MIDD evidence and if applicable MAP/MARs
- Products not within scope will follow a standard SA procedure
- CAP: Max 2 MIDD SA procedures per month
- Products out of scope or beyond cap will convert to a standard SA

Resources

- Specific M&S expertise in both coordinators' teams + clinical, statistics, nonclinical, quality as needed

Procedure

- Identical to a **Day 70 SA** with the participation of M&S experts in the SAWP plenary (or BWP plenary, if quality advice) and discussion meeting

MIDD Scientific Advice Pilot