Uncertainty quantification for complex models supporting regulatory decision making

First published: 21/08/2025

Last updated: 26/11/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000717

Study ID

1000000717

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Germany
- [ ] Sweden

Study description

Model-informed drug development (MIDD) plays a crucial role in drug development, and evaluation by regulatory agencies. A key component of MIDD is the use of complex mechanistic models, built on an understanding of physiology, drug characteristics, and pharmacology, to make extrapolations. However, these models often result in inadequate assessment of uncertainty due to their complexity and the sources of parameters.

This study aims to enhance drug development and regulatory decision-making by improving uncertainty quantification (UQ) methods for complex models.

The primary objectives are to assess existing UQ methods, conduct simulation studies to evaluate these methods, and develop a toolkit and tutorial for applying the best methods.

The methodology involves a comprehensive literature review to identify and summarize UQ methods, followed by simulation studies to test selected methods on use-cases such as drug-drug interactions and pediatric dosing.

The project will culminate in the development of user-friendly tools and tutorials for implementing UQ methods.

Study status

Ongoing

Research institutions and networks

Institutions

Uppsala University

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Medical University of Vienna

Austria

First published: 01/02/2024

Last updated: 26/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

University Medical Centre Göttingen (UMG)

Germany

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Institution | Hospital/Clinic/Other health care facility

Austrian Agency of Health and Food Safety

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Study timelines

Date when funding contract was signed

Actual: 18/04/2025

Study start date

Planned: 15/05/2025

Actual: 15/05/2025

Date of final study report

Planned: 17/08/2026

Sources of funding

- EMA

Study protocol

ROC22_CONFIRMS_Preliminary_Study_Plan.pdf (914.12 KB)

ROC22_CONFIRMS_Deliverable_3.pdf (706.55 KB)

Regulatory

Was the study required by a regulatory body?

Unknown

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Not applicable

Scope of the study:

Method development or testing

Documents

Study report

UQ_deliverable2_literature_review_report_final_RWD.pdf (2.37 MB)

ROC22 - EMASA EPAR Review - v1 RWD.pdf (1.45 MB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No