

Model-Informed Drug Development and Trial Simulation — Hands-on

Gain a conceptual yet practical view of model-informed drug development (MIDD) and trial simulation. This module shows how PopPK, PBPK and exposure–response models can be organised around decision questions, and how trial simulation thinking is used to explore doses, designs and probabilities of success for development programs.

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Session 1

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MIDD Foundations & Decision Framework

What is model-informed drug development and where it is used

early, late and lifecycle decisions **dose, schedule**
and patient selection **regulatory and labeling support**
themes

MIDD pillars at a conceptual level

PopPK and exposure–response ideas **PBPK and trial**

simulation themes **disease and systems models**
conceptually

Decision framework: question → model → evidence → action

clarifying decision and time line **choosing fit-for-**
purpose models **presenting results to cross**
functional teams

Session 2

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Linking Models, Endpoints & Questions

Translating clinical and development questions into model tasks

can the dose be reduced or simplified **which patients**
benefit most **what is the expected variability in**
response

Choosing exposure metrics and clinical endpoints (conceptual)

Cmax, AUC, Ctrough themes **efficacy and safety**
endpoints **composite and time to event ideas**

Organising existing PopPK, PBPK and ER models for decisions

mapping models to development stages **identifying**
data gaps and assumptions **documenting context of**
use clearly

Session 3

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Trial Simulation Concepts & Scenarios

Why simulate trials? Questions trial simulation can explore

dose and schedule comparisons **sample size and**
power themes **impact of adherence and dropouts**

Core concepts of clinical trial simulation (high level)

virtual patients and variability **generating exposure and response data** **estimating probability of technical success**

Example scenarios for MIDD and trial simulation

dose finding and confirmatory trials **enrichment and adaptive ideas conceptually** **special populations and paediatric themes**

Session 4

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Mini Capstone: MIDD Strategy & Trial Brief

Select a development decision and build an MIDD outline

describe decision and time line **list relevant models and data** **identify key assumptions and gaps**

Design a high level trial simulation plan (conceptual)

define virtual population and scenarios **clarify endpoints and success criteria** **outline outputs for decision meetings**

Deliverables: MIDD strategy slide deck and trial simulation brief

PDF or PPTX **ready for development or PMx review** **template for future MIDD projects**