Dr. Márton Kiss

Senior Statistician, Senior Clinical Research Manager

Physician and biostatistician with **9+** years of pharmaceutical industry experience skilled in pharmacometric modeling, adaptive trial design, and regulatory submissions (EMA, FDA). Experienced in dose-response analyses, and PK/PD studies. Expert in statistical programming (**R**), mixed-effects modeling, survival analysis, adaptive trial design and sample size estimation .

mrkmarton@gmail.com

06203478859

Budapest, Hungary

martonkissdr.hu/

linkedin.com/in/marton-kiss-md-29308a112

SKILLS

Pharmacokinetics (PK) | Physiologically-Based (PBPK) Modeling | Clinical programming | Clinical data interpretation | Clinical trial management (Phase I - IV) | Regulatory Submission (EMA, FDA) | Bioequivalence (BE) | Sample Size Calculation | Pharmacodynamics (PD) | Translational Modeling | Mixed-effects Modeling | Dose-Response Modeling | Data visualization | Clinical Trial Designs | SDTM & ADaM Dataset Use | Protocol development | Simulation Studies | Statistical analysis skills

WORK EXPERIENCE

Senior Clinical Research Manager (Full Time)

Egis Pharmaceuticals PLC

11/2016 - Present

Achievements/Tasks

- Conducted mechanistic **PBPK**, **PK/PD**, and **mixed-effects** modeling to support clinical pharmacokinetic projections, regulatory submissions, and clinical trial design for cardiovascular and topical therapeutics.
- Developed simulation-based **PBPK and translational modeling** frameworks, enabling accurate predictions for **drug-drug interactions (DDIs)** , pediatric, and other specific populations, enhancing clinical trial efficiency and regulatory compliance.
- Led statistical reanalyses for **bioequivalence** and **drug-drug interaction** studies, aligning outputs with evolving regulatory expectations.
- Provided strategic statistical and **pharmacometric** input into Scientific Advice Procedures (**pre-IND, IND**) to optimize clinical study designs and regulatory dossiers.
- Authored comprehensive Clinical Development Plans and Investigators Brochures integrating **mechanistic modeling approaches (PBPK, PK/PD)** to support regulatory strategy, clinical pharmacology studies, and product registration.
- Collaborated with cross-functional teams (**DMPK, Clinical Pharmacology, Regulatory Affairs**) to integrate **PBPK modeling and translational pharmacokinetics** into clinical development strategies and timelines.

WORK EXPERIENCE

Independent Consultant (Part-time)
self-employed

03/2021 - Present

*Roles included **Senior Statistician, Drug Safety Officer**, **Deputy QPPV** for a number of satisfied clients.*

Achievements/Tasks

- Served as **Senior Biostatistician** for 5+ adaptive clinical trials, employing advanced longitudinal modeling and advanced simulation methodologies.
- **Developed comprehensive Statistical Analysis Plans (SAPs)** and Clinical Study Reports (CSRs), overseeing all statistical programming deliverables to ensure high-quality, regulatory-compliant outputs.
- **Provided expert statistical consultation**, specifically in real-world evidence generation, causal inference methods, and post-authorization safety studies (PASS).
- Developed tentative, high-level **nonclinical development programs** for vaccine candidates, incorporating translational PK/PD and safety considerations to inform clinical development strategy.
- **Conducted statistical signal detection and safety data reviews** , reinforcing pharmacovigilance strategies and regulatory compliance for biologic products.
- Delivered strategic advice for complex **regulatory interactions and publication planning** , clearly translating complex statistical results for diverse stakeholders.

Drug Safety Specialist - Case Evaluator
Tata Consultancy Services

01/2016 - 11/2016

Achievements/Tasks

- Evaluated global Serious Adverse Event (**SAE**) cases for medical accuracy and regulatory compliance, enhancing understanding of clinical safety data handling.
- Gained proficiency with Argus database and **MedDRA** coding, contributing to pharmacovigilance and regulatory reporting skills.
- Assessed **event seriousness**, expectedness, and causality; ensured timely escalation according to SOPs.

EDUCATION

Applied Biostatistics
University of Veterinary Medicine

2018 - 2020 *Budapest*

Doctor of Medicine (M.D.)
Semmelweis University

2009 - 2015 *Budapest*

VOLUNTEER EXPERIENCE

Consultant
Clinical Trials Workgroup - Center for Translational Medicine, Semmelweis University

09/2024 - Present

Tasks/Achievements

- **Providing mentorship** in advanced clinical trial methodologies, sample size calculations, adaptive design, mixed-effects modeling, and regulatory strategies for early-career researchers.

HONOR AWARDS

Károly Pataki Memorial Competition (2022)

Egis Pharmaceuticals PLC

- 1st Place Award – Post-hoc Pharmacodynamic Analysis of Drug-Drug Interaction Study.

TECHNICAL SKILLS

Statistical Programming	Advanced R, Stan, saemix, familiarity with SAS, Python, JAGS	**Data Visualization**	ggplot2, R Shiny, interactive dashboards