

Burak Kürsad Günhan, PhD

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Experience

Merck Healthcare KGaA

Darmstadt, Germany

SENIOR BIOSTATISTICIAN

Jul. 2021 - Present

- Project lead biostatistician for a dual adenosine receptor antagonist: Safety Monitoring Committee core member for the phase Ia dose-escalation trial (design by a Bayesian model) and responsible for the development program.
- Trial biostatistician for phase I dose-escalation trials involving a DNA Damage Response. Several trials include multiple combinations and treatment schedules, thus innovative Bayesian designs are utilized.
- In-house consulting about Bayesian designs (trial protocols, and statistical analysis plan) for phase I dose-escalation trials

University Medical Center Göttingen

Göttingen, Germany

RESEARCH ASSOCIATE AND TEACHING ASSISTANT

Aug. 2016 - Jun. 2021

- Methodological research in Bayesian statistics applied in early/translational clinical trials and (network) meta-analysis, statistical programming, and teaching.

Galapagos NV

Mechelen, Belgium

BIOSTATISTICIAN INTERN

Aug. 2019 - Oct. 2019

- Developed a shrinkage estimation method for phase II trials with multiple treatment schedules.

Novartis Pharma AG

Basel, Switzerland

BIOSTATISTICIAN INTERN AT ONCOLOGY EARLY DEVELOPMENT

Aug. 2017 - Nov. 2017

- Developed a Bayesian method for simultaneously optimizing dose and schedule in phase I oncology dose-escalation trials and implemented in **Stan** and **R**

F. Hoffmann-La Roche AG

Basel, Switzerland

BIOSTATISTICIAN INTERN

Mar. 2016 - Jun. 2016

- Implemented nonlinear mixed effect models and pharmacokinetic pharmacodynamic models in **Stan**.

Education

University Medical Center Göttingen

Göttingen, Germany

PHD IN BIOSTATISTICS

Jan. 2017 - Dec. 2020

- Thesis: Bayesian methods for borrowing information in clinical drug development
- Supervisor: Prof. Dr. Tim Friede

University of Zurich

Zurich, Switzerland

MSC IN BIOSTATISTICS

Sept. 2013 - Jul. 2016

- Thesis: Network meta-analysis with integrated nested Laplace approximations
- Supervisors: Prof. Dr. Leonhard Held and Dr. Rafael Sauter

Bogazici University

Istanbul, Turkey

BSC IN MATHEMATICS

Sept. 2007 - Jul. 2012

Cross-industry and academic working groups

crmPack R package

MEMBER

Jan. 2022 - Present

- crmPack development Team consists of people across pharma, CRO and academia. Collaborative work using agile working principles: <https://github.com/Roche/crmPack/projects/6>

Paediatric phase I dose-escalation trials

PROJECT LEAD

Dec. 2021 - Present

- A collaboration between Merck KGaA and academia. Investigation of the statistical methodology for phase I dose-escalation trials in paediatric population.

Automated outputs for Safety Monitoring Committee meetings

MEMBER

Aug. 2021 - Present

- A collaborative work between biostatisticians, statistical programmers, and data scientist to automate outputs for Safety Monitoring Committee. From clinical raw data to powerpoint slides and HTML document are created thanks to developed (internal) R package.

Skills

| | |
|-----------------------------|---|
| Programming | R, Git/Github, Shiny, BASH |
| Document preparation | LaTeX, Rmarkdown, knitr |
| Bayesian inference | WinBUGS/JAGS, Stan, INLA |
| OS platform | Windows, Macintosh, Linux (Ubuntu) |
| Languages | English (Fluent), Turkish (Native), German (Intermediate) |

Publications

MetaStan: An R package for Bayesian (model-based) meta-analysis using Stan

B. K. Günhan, C. Röver, T. Friede

preprint ArXiv. (2022). URL: [HTTPS://ARXIV.ORG/ABS/2202.00502](https://arxiv.org/abs/2202.00502)

Phase I dose-escalation oncology trials with sequential multiple schedules

B. K. Günhan, S. Weber, A. Seroutou, T. Friede

BMC Medical Research Methodology (2021). URL: [HTTPS://DOI.ORG/10.1186/s12874-021-01218-9](https://doi.org/10.1186/s12874-021-01218-9)

Shrinkage estimation for dose-response modeling in phase II trials with multiple dose regimens

B. K. Günhan, P. Meyvisch, T. Friede

Statistics in Biopharmaceutical Research (2020). URL: [HTTPS://DOI.ORG/10.1080/19466315.2020.1850519](https://doi.org/10.1080/19466315.2020.1850519)

A Bayesian time-to-event pharmacokinetic model for phase I dose-escalation trials with multiple schedules

B. K. Günhan, S. Weber, T. Friede

Statistics in Medicine (2020). URL: [HTTPS://DOI.ORG/10.1002/sim.8703](https://doi.org/10.1002/sim.8703)

Random-effects meta-analysis of few studies involving rare events

B. K. Günhan, C. Röver, T. Friede

Research Synthesis Methods (2019) PP. 1–17. URL: [HTTPS://DOI.ORG/10.1002/jrsm.1370](https://doi.org/10.1002/jrsm.1370)

A design-by-treatment interaction model for network meta-analysis and meta-regression with integrated nested Laplace approximations

B. K. Günhan, T. Friede, L. Held

Research Synthesis Methods 9.2 (2018) PP. 179–194. URL: [HTTPS://DOI.ORG/10.1002/jrsm.1285](https://doi.org/10.1002/jrsm.1285)

Recent advances in methodology for clinical trials in small populations: the InSPiRe project

T. Friede, M. Posch, S. Zohar, and 19 others including B. K. Günhan

Orphanet Journal of Rare Diseases 13.1 (2018). URL: [HTTPS://DOI.ORG/10.1186/s13023-018-0919-y](https://doi.org/10.1186/s13023-018-0919-y)

Software packages

MetaStan: Bayesian Meta-Analysis via ‘Stan’

DEVELOPER AND MAINTAINER

2018

<https://CRAN.R-project.org/package=MetaStan>

nmaINLA: An R package for fitting Bayesian network meta-analysis models using INLA

DEVELOPER AND MAINTAINER

2017

<https://CRAN.R-project.org/package=nmaINLA>

Presentations

ORAL PRESENTATIONS

Annual Conference of the International Society for Clinical Biostatistics

Newcastle, UK

A COLLABORATIVE APPROACH TO SOFTWARE DEVELOPMENT: THE CRMPACK EXPERIENCE

Aug. 2022

Oliver Boix, B. K. Günhan, and crmPack development Team

Annual Meeting Society for Clinical Trials

Online

A BAYESIAN TIME-TO-EVENT PHARMACOKINETIC MODEL FOR PHASE I DOSE-ESCALATION TRIALS WITH MULTIPLE SCHEDULES

Aug. 2022

Burak Kürsad Günhan

GMDS and CEN-IBS 2020

Online

SHRINKAGE ESTIMATION FOR DOSE-RESPONSE MODELING IN PHASE II TRIALS WITH MULTIPLE DOSE REGIMENS

Sept. 2020

Applied Bayesian Biostatistics Conference

Lyon, France

MODEL-BASED META-ANALYSIS USING ARM-BASED MODELS

May. 2019

Workshop of the IBS-DR working group “Bayes Methods”

PHASE I DOSE-ESCALATION TRIALS WITH MORE THAN ONE DOSING REGIMEN

Göttingen, Germany

Dec. 2018

64. Biometrisches Kolloquium, International Biometric Society (German Region)

A DESIGN-BY-TREATMENT INTERACTION MODEL FOR NETWORK META-ANALYSIS AND META-REGRESSION WITH INTEGRATED NESTED LAPLACE APPROXIMATIONS,

Frankfurt, Germany

Mar. 2018

POSTER PRESENTATIONS

International Biometric Conference (IBC)

GUIDING PHASE I DOSE-ESCALATION TRIALS WITH MORE THAN ONE DOSING REGIMEN

Barcelona, Spain

Jul. 2018

Statisticians in the Pharmaceutical Industry (PSI)

META-ANALYSIS OF RARE EVENTS WITH FEW STUDIES

Amsterdam, Netherlands

Jun. 2018

Teaching

Analysis of Time-to-Event data

MSC. IN APPLIED STATISTICS, GEORG-AUGUST UNIVERSITY OF GÖTTINGEN

Fall Semester

2018/19, 2019/20

Introduction to Statistics

MSC. IN NEUROSCIENCE, GEORG-AUGUST UNIVERSITY OF GÖTTINGEN

Fall Semester

2017/18, 2018/19, 2019/20, 2020/21