Burak Kürsad **Günhan, PhD**

burakgunhan@gmail.com | www.bkguenhan.com | gunhanb | gunhanb

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 planning of the probability of success of later development including phase Ib expansion trial.
- 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 HTLM 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 platfrom	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

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

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

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

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

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

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

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" — *Göttingen, Germany*

Phase I dose-escalation trials with more than one dosing regimen — *Dec. 2018*

64. Biometrisches Kolloquium, International Biometric Society (German Region) — *Frankfurt, Germany*

A design-by-treatment interaction model for network meta-analysis and meta-regression with integrated nested Laplace approximations, — *Mar. 2018*

Poster presentations

International Biometric Conference (IBC) — *Barcelona, Spain*

Guiding phase I dose-escalation trials with more than one dosing regimen — *Jul. 2018*

Statisticians in the Pharmaceutical Industry (PSI) — *Amsterdam, Netherlands*

Meta-analysis of rare events with few studies — *Jun. 2018*

Teaching

Analysis of Time-to-Event data — *Fall Semester*

MSc. in Applied Statistics, Georg-August University of Göttingen — *2018/19, 2019/20*

Introduction to Statistics — *Fall Semester*

MSc. in Neuroscience, Georg-August University of Göttingen — *2017/18, 2018/19, 2019/20, 2020/21*