Burak Kürsad Günhan, PhD

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Experience

Merck Healthcare KGaA Darmstadt, Germany

SENIOR BIOSTATISTICIAN

Jul. 2021 - Present

- Project Biostatistician for a dual adenosine receptor antagonist project. Core member of the Safety Monitoring Committee for Phase Ia doseescalation trial, utilizing Bayesian model design. Instrumental in strategizing the probability of success for subsequent stages, including the Phase Ib expansion trial.
- Served as the trial biostatistician for multiple Phase I dose-escalation trials in DNA Damage Response. These trials featured various combinations and treatment schedules, necessitating the use of innovative Bayesian designs for optimal outcomes.
- Provided in-house consultancy on Bayesian design principles, including trial protocol development and statistical analysis planning, specifically 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.

FEBRUARY 3, 2024 BURAK KÜRSAD GÜNHAN · RÉSUMÉ

Automated outputs for Safety Monitoring Committee meetings

EMBER 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

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://ddi.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

 $\textit{Research Synthesis Methods} \ 9.2 \ (2018) \ \texttt{PP.} \ 179-194. \ \texttt{URL:} \ \texttt{HTTPS:} \ \texttt{.} / \texttt{DOI.org} / 10.1002 / \texttt{JRSM.} \ 1285$

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 Mar. 2018

NESTED LAPLACE APPROXIMATIONS,

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