CURRICULUM VITAE

PERSONAL

Name:	Dr. Sabine Lauer (nee Ricker)
Adress:	Neuhöfer Straße 43a
	D-63263 Neu-Isenburg, Germany
Date of birth:	8-April-1972
E-mail:	sabine.lauer@drlauer-research.com

PROFESSIONAL

since Apr 2010	Dr. Lauer Research, Neu-Isenburg, Germany FREELANCE BIOSTATISTICIAN
Aug 2006 - Mar 2010	Accovion GmbH, Eschborn, Germany SENIOR BIOSTATISTICIAN
Jan 2006 - Jun 2006	Merz Pharmaceuticals GmbH, Frankfurt/Main, Germany BIOSTATISTICIAN
Dec 2002 - Dec 2005	Accovion GmbH, Eschborn, Germany BIOSTATISTICIAN
Apr 2001 - Nov 2002	SECUDE GmbH, Darmstadt, Germany CONSULTANT FOR CRYPTOGRAPHIC APPLICATIONS

Study statistician for various clinical trials (phase II-IV and observational studies, including trials with an adaptive design), involved in all statistical activities such as

- Protocol writing, (e)CRF design, Data surveillance
- Writing of statistical analysis plans
- Design, programming and validation of tables, listings, and graphs
- Writing of clinical study reports, annual safety reports and publications

Further experience

- Interactions with regulatory authorities including preparation of submission dossiers, preparation and attendance of meetings, response to questions
- Principal stratum analyses for immunogenicity (anti-drug-antibodies)
- Meta-analyses
- Analyses evaluating the predictive and prognostic value of *biomarkers for cardiac events* and development of a *heart failure risk score*
- Prediction of probability of final trial success after interim analysis
- Event-prediction
- Independent statistician for the data monitoring committee of two *thalassaemia studies*
- Member of the data monitoring committee for a study in *mitral valve repair surgery*

Project leader of numerous projects with responsibility for the following main tasks:

- Coordination and leadership of team members
- Key contact person for client requests
- Financial tracking and management of timelines and resources

Experience as a statistician and/or project leader in various indications, including *breast cancer, cardiovascular disease, fabry disease, pain, migraine, epilepsy, spasticity, multiple sclerosis, osteoarthritis, dementia, colon cancer,* and *diabetes.*

In-depth programming skills in SAS/SAS-MACRO, advanced skills in R, and familiar with the use of statistical software like NQuery, LogXact, StatXact, Pass, and Addplan.

EDUCATION

1999 – 2001	Johann Wolfgang Goethe-University, Frankfurt am Main, Germany Ph.D in Mathematics
1998 – 1999	Oregon State University, Corvallis, Oregon, USA Research stay at the Department of Mathematics
1996 – 1999	Studienstiftung des deutschen Volkes Scholarship holder
1993 – 1998	Johann Wolfgang Goethe-University, Frankfurt am Main, Germany Masters degree in Mathematics

German native speaker, fluent in English and French (both spoken and written)

SELECTED TRAINING AND CONFERENCES

2022 Basel Biometric Section (BBS) Virtual Seminar, *Machine learning in clinical drug development*

2021 Arbeitsgruppe Pharmazeutische Forschung Virtual Workshop, B*reakthrough Therapies*

2020 Basel Biometric Section (BBS) Virtual Seminar, *Impact of COVID-19 on clinical trials*

2019 Austro-Swiss Region of the international biometric society and Medical University of Vienna, *Workshop on Bayesian Clinical Trials*

2018 64. Biometrisches Kolloquium, Goethe-Universität Frankfurt/Main
Biometrie: Gelebte Vielfalt

2017 European Federation of Statisticians in the Pharmaceutical Industry (EFPSI): Basel, Switzerland *Workshop on Regulatory Statistics*

International Biometric Society (IBS): Berlin, Germany
Analysis of multiple event-times: recurrent events and combined endpoints

2015 PhUSE annual conference: Vienna, Austria
Best presentation award in the Statistics & Pharmacokinetics stream for *„Adjusting long-term efficacy estimates when patients cross over to experimental treatment"*

2014 Arbeitsgruppe Pharmazeutische Forschung: München, Germany
Subgroup analyses and experiences with the missing data guideline

2013 International Biometric Society (IBS): Berlin, Germany
Multiple testing procedures in clinical trials

2010 Statisticians in the Pharmaceutical Industry (PSI) E-Learning
James Carpenter Multiple Imputation Course

2009 Medical and Pharmaceutical Statistics Research Unit (MPS): Lancaster University, United Kingdom
Adaptive and bayesian methods in clinical research

2007 Multiple Comparison Procedures (MCP): Vienna, Austria
5th international conference on multiple comparisons

2006 International Biometric Society (IBS): Berlin, Germany
Workshop on *adaptive designs*

2005 IBS: Universität Halle, Germany
Tutorial *Interim monitoring of clinical trials*

2004 MPS: University of Reading, United Kingdom.
Statistical analysis of categorical data

2003 MPS: University of Reading, United Kingdom.
Meta-analysis of controlled clinical trials

PUBLICATIONS

Anker et al. *„Empagliflozin in patients with type 2 diabetes mellitus and chronic obstructive pulmonary disease"*, Diabetes Research and Clinical Practice (Apr 2022)

Kong et al. *„Weighted approach for estimating Effects in principal strata with missing data for a categorical post-baseline variable in randomized controlled trials"*, Statistics in Biopharmaceutical Research (Jan 2022)

Ferreira et al. *„Cardio/Kidney Composite End Points: A Post Hoc Analysis of the EMPA-REG OUTCOME Trial"*, American Journal of Hypertension (Dec 2021)

Ferreira et al. *„Empagliflozin for patients with presumed resistant hypertension: a post hoc analysis of the EMPA-REG OUTCOME trial"*, Journal American Heart Association (Dec 2020)

Ferreira et al. *„Metabolic syndrome in patients with type 2 diabetes and atherosclerotic cardiovascular disease: a post hoc analysis of the EMPA-REG OUTCOME trial"*, Cardiovascular Diabetology (Nov 2020)

Lidbrink et al. *„A real-world study of cardiac events in >3700 patients with HER2-positive early breast cancer treated with trastzumab: final analysis of the OHERA study."* Breast Cancer Research and Treatment (Nov 2018)

Gligorov J et al. *"Switching between intravenous and subcutaneous trastuzumab: Safety results from the PrefHer trial"*, Breast. (Aug 2017), pages 89-95

Cameron D et al.*"11 years' follow-up of trastuzumab after adjuvant chemotherapy in HER2-positive early breast cancer: final analysis of the HERceptin Adjuvant (HERA) trial"*, Lancet (Mar 2017), pages 1195-1205

Zardavas D et al. *"Role of Troponins I and T and N-Terminal Prohormone of Brain Natriuretic Peptide in Monitoring Cardiac Safety of Patients with Early-Stage Human Epidermal Growth Factor Receptor 2-positive Breast Cancer Receiving Trastuzumab: A Herceptin Adjuvant Study Cardiac Marker Substudy"*, Journal of Clinical Oncology (Mar 2017), pages 878-884

Sabine Ricker *"Symmetric Fuchsian quadrilateral groups and modular embeddings"*, Quart. J.Math. 53 (2002), pages 75-86

Neu-Isenburg, den 5. August 2022

S. Zaun