

Name: Dr. Sabine Lauer (nee Ricker)
 E-mail: sabine.lauer@drlauer-research.com

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, validation and statistical review of tables, listings, and graphs
- Writing of clinical study reports, lay summaries, annual safety reports and publications

Further experience

- Meta-analyses/Integrated summaries
- Bayesian modeling of dose-response relationship in a dose escalation and expansion trial (Phase Ia/b)
- Interactions with regulatory authorities including preparation of submission dossiers, preparation and attendance of meetings, response to questions
- Analyses evaluating the predictive and prognostic value of biomarkers for cardiac events and development of a heart failure risk score
- Principal stratum analyses for immunogenicity (anti-drug-antibodies)
- Prediction of probability of final trial success after interim analysis
- Event-prediction
- Independent statistician as well as statistical member of data monitoring committees

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 *lung cancer, hemophilia B, 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 and advanced skills in R.

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)

- 2026** IBS Webinar: Is repeated Bayesian interim analysis consequence-free?
- 2025** EFPSI Regulatory statistics workshop (virtual attendance)
- 2024** Arbeitsgruppe Pharmazeutische Forschung: München, Germany
Drug development in rare diseases
- 2023** Basel Biometric Section (BBS) Virtual Seminar
Quantification of risk: ask the right questions or time to apply the estimand framework to safety
- 2022** Basel Biometric Section (BBS) Virtual Seminar
Machine learning in clinical drug development
- 2021** Arbeitsgruppe Pharmazeutische Forschung Virtual Workshop
Breakthrough 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
- 2017** 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

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 trastuzumab: 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