

Curriculum Vitae

Kaspar Rufibach, PhD
Biostatistician

Last updated: 7th September 2020

PROFESSIONAL EXPERIENCE:

- 07/2015 – Methods, Collaboration, and Outreach group, Biostatistics, F. Hoffmann-La Roche Ltd, Basel, Switzerland (on 50% rotation from 07/2015 - 12/2016, full time 90% since 01/2017)
- Small group of statisticians serving as point of contact for methodological and drug development questions within Roche Biostatistics and beyond.
 - Develop fit-for-purpose methodology and software.
 - Contribute to cross-industry and academic working groups.
 - Mentoring interns.
 - Provide trainings to Statisticians and non-Statisticians, in- and externally.
 - Job titles at Roche: Statistical Scientist (05/2012 - 03/2015), Senior Statistical Scientist (04/2015 - 03/2017), Principal Statistical Scientist (04/2017 - 05/2019, technical equivalent to Associate Director of Biostatistics), Senior Principal Statistical Scientist (06/2019 - 04/2020, not a promotion but a rebranding of Roche job titles), Expert Statistical Scientist (since 05/2020, technical equivalent to Director of Biostatistics).
- 05/2012 – 12/2016 Trial and project statistician (full time until 02/2014, 90% since 03/2014), Biostatistics oncology, F. Hoffmann-La Roche Ltd, Basel, Switzerland
- Study statistician for a large Phase III registration trial in the GAZYVA development program. Biometrics subteam lead for global filing.
 - Project lead statistician for MDM2(4): Planning of Phase 1 dose-finding and pivotal Phase III trial.
- 02/2012 – Founder and owner, Rufibach rePROstat - consulting and education in biostatistics, Bern, Switzerland
- Statistical consulting of medical researchers.
 - Trainings in Biostatistics for various audiences.
 - Teaching in Master of advanced studies program at University of Applied Sciences, Winterthur.

- 11/2007 – 12/2011 Lecturer in Biostatistics (100%), Division of Biostatistics, Institute of Social and Preventive Medicine (ISPMZ), University of Zurich, Switzerland
- Methodological research in statistics.
 - Teaching of biostatistics and medicine master students.
 - Statistical consulting of medical researchers.
- 09/2006 – 08/2007 Postdoctoral scholar, Department of Statistics, Stanford University, Palo Alto, United States (Swiss National Science Foundation fellowship)
- Methodological research in statistics.
 - Collaboration with neurologists.
- 03/2002 – 04/2006 Biostatistician (40%–50%), Swiss Group for Clinical Cancer Research (SAKK), Bern, Switzerland
- Statistician for Phase II / III oncology trials.
- 11/2000 – 08/2006 Research and Teaching Assistant (25–50%), Department of Mathematical Statistics and Actuarial Science (IMSV), University of Bern, Switzerland
- Methodological research in statistics.
 - Teaching and mentoring students.
 - Statistical consulting.

EDUCATION:

- 09/2006 – 08/2007 Postdoctoral scholar, Department of Statistics, Stanford University, Palo Alto, United States.
Project: *Quantifying heterogeneity in flow cytometry measurements and applications of log-concave density estimation.*
Collaborator: Prof. Günther Walther.
- 04/2002 – 05/2006 PhD in Mathematics (magna cum laude), Department of Mathematical Statistics and Actuarial Science, University of Bern, Switzerland and Institute of Mathematical Statistics, Georg-August-University, Göttingen, Germany. Thesis: *Log-concave density estimation and bump hunting for i.i.d. observations.* Advisors: Prof. Lutz Dümbgen (Bern) and Prof. Axel Munk (Göttingen).
- 10/1997 – 11/2001 Diploma in Statistics (cum laude), Minors in Mathematics and Economics, Department of Mathematical Statistics and Actuarial Science, University of Bern, Switzerland.
Thesis: *Phase reconstructions for uniform distributions in \mathbb{R}^d (in German).* Advisor: Prof. Henri Carnal.

AWARDS:

- 01/08/11 Certificate of Distinction. Awarded by the journal “Skeletal Radiology” for that the quantity, timeliness, and quality of referee reports during 2010 was above and beyond the call of duty.
- 10/08/10 Certificate of Distinction. Awarded by the journal “Skeletal Radiology” to top 15% of referees for quality of referee reports during 2009.

- 25/01/10 – 29/01/10 Invitation to workshop “Statistical Issues in Prediction: What can be Learned for Individualized Predictive Medicine?”. Mathematisches Forschungsinstitut, Oberwolfach, Germany.
- 06/11/06 – 10/11/06 Invitation to workshop “Qualitative Assumptions and Regularization in High-Dimensional Statistics”. Mathematisches Forschungsinstitut, Oberwolfach, Germany.
- 04/12/06 Moser-Prize of the Institute of Mathematical Statistics and Actuarial Science, University of Bern. Awarded for the best Diploma or PhD thesis of the year 2006. SFr 1,000.
- 18/07/05 – 23/07/05 Participation in European young statisticians training camp, Oslo (50 participants selected out of 120). All expenses covered.

FACE-TO-FACE HEALTH AUTHORITY MEETINGS:

- 20/08/2020 FDA meeting within Complex Innovative Design (CID) pilot program. *Discuss CID proposal for a study with dynamic borrowing for OS (held as TC b/c of COVID-19 epidemic).*
- 13/11/2019 MHRA London. *Regular meeting between MHRA statisticians and EFSPi regulatory statistics committee.*
- 27/10/2017 EMA Biostatistics Working Party. *Regular meeting between EMA statisticians and EFSPi regulatory statistics committee.*
- 23/11/2016 MHRA London. *Regular meeting between MHRA statisticians and EFSPi regulatory statistics committee.*
- 28/07/2016 FDA sBLA meeting. *Discuss Gallium submission.*
- 08/07/2016 ANSM France. *Discuss Gallium submission.*
- 08/07/2015 CHMP Scientific Advice Working Party (SAWP) meeting. *Discuss Idasanutlin Phase 3 study.*
- 27/01/2015 FDA Type B Meeting. *Discuss Idasanutlin Phase 3 study.*

CROSS-INDUSTRY AND ACADEMIC WORKING GROUPS:

- 01/2018 - Oncology estimand working group (initiator and leader). *Cross-industry working group initiated by Evgeny Degtyarev (Novartis) and myself, working on guidelines how to implement the ICH E9 addendum for time-to-event endpoints. Status as both, EFSPi scientific interest group and ASA biopharmaceutical section scientific working group. Working group webpage: www.oncoestimand.org.*
- 07/2017 - Analysis of adverse events with varying follow-up times (member and member of the steering committee). *Working group with members from academia, industry, and regulators with the goal of evaluating different methods to analysis adverse events with varying follow-up times.*
- 04/2017 - 09/2018 Neuroscience estimand working group (member). *Working group with the goal of developing estimand strategies in neuroscience.*
- 06/2016 - 01/2018 RPACT, sub-working group of the AG Statistikleitertreffen of the German Region of the IBS (member). *Industry consortium supporting development of **rpact**, a R package implementing group-sequential and adaptive designs.*
- 11/2015 - EFSPi regulatory working group (member). *EFSPi special interest group: review of regulatory guidelines, collaboration with EFPIA, regular meetings with regulators.*

REFEREEING:

Online list of performed reviews (statistical journals only): Publons

Reviewer for statistical journals

Annals of Applied Statistics (2011: 1), Annals of Statistics (2006: 1, 2011: 1), Biometrical Journal (2008: 1, 2010: 2, 2018: 1, 2019: 1), Biometrika (2010: 1), Computational Statistics and Data Analysis (2010: 1), Electronic Journal of Statistics (2010: 1, 2012: 1), Journal of Nonparametric Statistics (2008: 1), Journal of Statistical Software (2011: 1), Pharmaceutical Statistics (2017: 1, 2018: 2, 2019: 3, 2020: 3), Scandinavian Journal of Statistics (2005: 1), Statistica Neerlandica (2009: 1), Statistica Sinica (2011: 1), Statistics in Medicine (2011: 1, 2017: 1, 2018: 2), Statistics in Biopharmaceutical Research (2018: 1, 2019: 3, 2020: 1), PLOS ONE (2018: 1).

External statistical expert for Skeletal Radiology

2008: 7 expertises. 2009: 10 expertises. 2010: 7 expertises. 2011: 2 expertises.

Reviewer for medical journals

BMC Medicine (2020: 1), Contemporary Clinical Trials (2008: 1), Critical Care Medicine (2008: 1).

Reviewer for funding agencies

Netherlands Organisation for Scientific Research (2008: 1), Medical Research Council UK (2019: 1).

Reviewer book proposals

Chapman & Hall/CRC (2015: 1).

PROFESSIONAL SERVICE:

2021	67th Biometric Colloquium of the German Region of International Biometric Society (IBS): Member of scientific committee.
2020	5th EFSPi Regulatory Statistics Workshop: Member of scientific and local organizing committee.
2019 - 2019	Basel Biometric Section: Member of the board. 4th EFSPi Regulatory Statistics Workshop, Basel: Member of scientific and local organizing committee.
2018	3rd EFSPi Regulatory Statistics Workshop, Basel: Member of scientific and local organizing committee.
2017 -	Region Austria-Switzerland of the International Biometric Society: Accounting Auditor.
2017	2nd EFSPi Regulatory Statistics Workshop, Basel: Member of scientific and local organizing committee.
2009	Swiss Statistics Meeting, Geneva: Member of organizing committee.

PROFESSIONAL MEMBERSHIPS:

International Biometric Society (IBS, Austro-Swiss Region), International Society for Clinical Biostatistics (ISCB), Swiss Statistical Society (SSS).

REFERENCES:

Available upon request.