Curriculum Vitae

Kaspar Rufibach, PhD
Biostatistician

Last updated: 19$^{\text{th}}$ October, 2019

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 questions within Roche Biostatistics.

- 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.

- Consulting for Roche Biostatisticians.

- Job titles at Roche: Statistical Scientist (05/2012 - 03/2015), Senior Statistical Scientist (04/2015 - 03/2017), Principal Statistical Scientist (04/2017 - 05/2019), Senior Principal Statistical Scientist (since 06/2019, not a promotion but a rebranding of Roche job titles).

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:

27/10/2017	EMA Biostatistics Working Party. *Regular meeting between EMA statisticians and EFSPI regulatory committee.*
23/11/2016	MHRA London. *Regular meeting between MHRA statisticians and EFSPI regulatory 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.*
07/2017 -	Analysis of adverse events with varying follow-up times (member). *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 -	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), 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), 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), 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
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:

2019	Member of scientific and local organizing committee, 4th EFSPI Regulatory Statistics Workshop, Basel.
2018	Member of scientific and local organizing committee, 3rd EFSPI Regulatory Statistics Workshop, Basel.
2017 -	Region Austria-Switzerland of the International Biometric Society: Accounting Auditor.
2017	Member of scientific and local organizing committee, 2nd EFSPI Regulatory Statistics Workshop, Basel.
2009	Member of organizing committee, Swiss Statistics Meeting, Geneva.

Professional Memberships:

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

References:
Available upon request.