

# Curriculum Vitae

Kaspar Rufibach, PhD  
Biostatistician

Last updated: 5<sup>st</sup> October 2020

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## 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.

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| 11/2007 – 12/2011 | <p>Lecturer in Biostatistics (100%), Division of Biostatistics, Institute of Social- and Preventive Medicine (ISPMZ), University of Zurich, Switzerland</p> <ul style="list-style-type: none"> <li>• Methodological research in statistics.</li> <li>• Teaching of biostatistics and medicine master students.</li> <li>• Statistical consulting of medical researchers.</li> </ul> |
| 09/2006 – 08/2007 | <p>Postdoctoral scholar, Department of Statistics, Stanford University, Palo Alto, United States (Swiss National Science Foundation fellowship)</p> <ul style="list-style-type: none"> <li>• Methodological research in statistics.</li> <li>• Collaboration with neurologists.</li> </ul>  |
| 03/2002 – 04/2006 | <p>Biostatistician (40%–50%), Swiss Group for Clinical Cancer Research (SAKK), Bern, Switzerland</p> <ul style="list-style-type: none"> <li>• Statistician for Phase II / III oncology trials.</li> </ul>   |
| 11/2000 – 08/2006 | <p>Research and Teaching Assistant (25–50%), Department of Mathematical Statistics and Actuarial Science (IMSV), University of Bern, Switzerland</p> <ul style="list-style-type: none"> <li>• Methodological research in statistics.</li> <li>• Teaching and mentoring students.</li> <li>• Statistical consulting.</li> </ul>  |

## EDUCATION:

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

## AWARDS:

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| 01/08/11 | <p>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.</p> |
| 10/08/10 | <p>Certificate of Distinction. Awarded by the journal “Skeletal Radiology” to top 15% of referees for quality of referee reports during 2009.</p>   |

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

#### CROSS-INDUSTRY AND ACADEMIC WORKING GROUPS:

01/2018 -	Oncology estimand working group (initiator and leader). <i>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: <a href="http://www.oncoestimand.org">www.oncoestimand.org</a>.</i>
07/2017 -	Analysis of adverse events with varying follow-up times (member and member of the steering committee). <i>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.</i>
04/2017 - 09/2018	Neuroscience estimand working group (member). <i>Working group with the goal of developing estimand strategies in neuroscience.</i>
06/2016 - 01/2018	RPACT, sub-working group of the AG Statistikleitertreffen of the German Region of the IBS (member). <i>Industry consortium supporting development of <b>rpact</b>, a R package implementing group-sequential and adaptive designs.</i>
11/2015 -	EFSPi regulatory working group (member). <i>EFSPi special interest group: review of regulatory guidelines, collaboration with EFPIA, regular meetings with regulators.</i>

## 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.