Curriculum Vitae

Kaspar Rufibach, PhD Biostatistician http://www.kasparrufibach.ch

Last updated: 31st July 2024

Professional experience:

07/2015 - 07/2024

Methods, Collaboration, and Outreach group, Product Development Data Sciences, 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), Senior Principal Statistical Scientist (06/2019 04/2020, not a promotion but a rebranding of Roche job titles), Expert Statistical Scientist (since 05/2020).

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.

11/2007 - 12/2011

Lecturer in Biostatistics (100%), Division of Biostatistics, Institute of Socialand 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:

 $09/2006 - 08/2007 \qquad \text{Postdoctoral scholar, Department of Statistics, Stanford University, Palo Alto,} \\$

United States.

Project: Quantifying heterogeneity in flow cytometry measurements and appli-

cations of log-concave density estimation.

Collaborator: Prof. Günther Walther.

04/2002 - 05/2006 PhD in Mathematics (magna cum laude), Department of Mathematical Statis-

tics 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:

01/12/21 Industry/University Cooperation Award. University of Ulm, prize awarded

for long-term scientific collaboration between Jan Beyersmann (Prof. Bio-

statistics at University of Ulm) and Kaspar Rufibach (Roche).

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. |
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| 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. |

| Cross-industry and academic working groups: | | |
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| 09/2023 - | EFSPI statistical methodology leaders (co-lead). Initiator and co-lead together with Cornelia Kunz (Boehringer Ingelheim) and Mouna Akacha (Novartis). | |
| 05/2022 - | NIHR-MRC Trials Methodology Research Partnership (TMRP) Outcomes Working Group: Adverse Events - evaluating harm (lead of estimand workstream). Academia-industry working group with the goal of improving analysis of safety data in clinical trials. | |
| 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). <i>Industry consortium supporting development of</i> rpact , a R package implementing group-sequential and adaptive designs. | |
| 11/2015 - 12/2022 | 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): Web of science

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, 2020: 1, 2022: 1, 2024: 1), Biometrika (2010: 1), BMC Medical Research Methodology (2023: 1), British Journal of Clinical Pharmacology (2022: 1), Computational Statistics and Data Analysis (2010: 1), Contemporary Clinical Trials (2023: 1), Electronic Journal of Statistics (2010: 1, 2012: 1), Journal of Biopharmaceutical Statistics: (2021: 2, 2022: 1), Journal of Nonparametric Statistics (2008: 1), Journal of Statistical Software (2011: 1), JRSS-C (2021: 1), Pharmaceutical Statistics (2017: 1, 2018: 2, 2019: 3, 2020: 5, 2021: 1, 2023: 1, 2024: 1), Scandinavian Journal of Statistics (2005: 1), Statistica Neerlandica (2009: 1), Statistica Sinica (2011: 1), Statistical Papers (2023: 1), Statistics in Medicine (2011: 1, 2017: 1, 2018: 2, 2021: 2, 2022: 2, 2023: 2), Statistics in Biopharmaceutical Research (2018: 1, 2019: 4, 2023: 3), The American Statistician (2022: 1), Therapeutic Innovation & Regulatory Science (2023: 1, 2024: 1), PLOS ONE (2018: 1).

External statistical expert for Skeletal Radiology

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

Statistical reviewer for medical journals

Anesthesiology (2023: 1), BMC Medicine (2020: 2), Contemporary Clinical Trials (2008: 1), Critical Care Medicine (2008: 1), Trials (2021: 1).

Reviewer for funding agencies

Agence Nationale de la recherche, France (2023: 1), Netherlands Organisation for Scientific Research (2008: 1), Medical Research Council UK (2019: 1).

Reviewer book proposals

Chapman & Hall/CRC (2015: 1).

PROFESSIONAL SERVICE:

| 2025 | ISCB46 conference in Basel: co-chair (with Mouna Akacha from Novartis) of organizing committee. |
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| 2024 - | EFSPI, council member. |
| 2017-2019, 2023 - | EFSPI Regulatory Statistics Workshop, Basel: Member of scientific and local organizing committee. |
| 2020 - 2022 | EFSPI Regulatory Statistics Workshop: Lead of scientific and local organizing committee. |
| 2019 - | Basel Biometric Section: Member of the board. |
| 2017 - | Region Austria-Switzerland of the International Biometric Society: Accounting Auditor. |
| 2023 | ISCB44 Milan, Italy: Member of scientific committee. |
| 2021 | 67th Biometric Colloquium of the German Region of International Biometric Society (IBS): Member of scientific 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.