Presentations

Kaspar Rufibach, PhD Biostatistician

Last updated: $10^{\rm th}$ March 2021

ODGANIE ATTON OF	CENTINA	AND COMPEDENCE	GEGGEONG.
ORGANIZATION OF	F SEIVIINARS	AND CONFERENCE	SESSIONS:

21/09/2021	ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop, Rockville, USA. Clinical and Statistical Perspectives on Post-ICH E9 (R1) Addendum Estimand Use: Current Status and Future Directions (jointly organized with Lei Nie and Shanti Gomatam, both FDA).
07/09/2021	Bi-annual conference of the Austrian-Swiss Region of the IBS, Salzburg, Austria. <i>How can statistics help to disrupt drug development? (jointly organized with Marcel Wolbers).</i>
15/03/2021	Bi-annual conference of the German Region of the IBS, Münster, Germany (virtual event). Drug development beyond traditional paths: how can pharma and academia best collaborate to address today's drug development challenges? (jointly organized with Cornelia-Ursula Kunz).
07/09/2020	Seminar of the Basel Biometrics Section, Basel, Switzerland. RCTs meeting causal inference: principal stratum strategy and beyond (jointly organized with Björn Bornkamp and Giusi Moffa).
06/09/2020	Joint conference of the GMDS & CEN-IBS 2020, Berlin, Germany. How can statistics help to disrupt drug development? (jointly organized with Marcel Wolbers). Cancelled because of COVID-19 epidemic.
06/09/2020	Joint conference of the GMDS & CEN-IBS 2020, Berlin, Germany. One year of ICH E9 addendum - examples of application and open problems (jointly organized with Evgeny Degtyarev). Cancelled because of COVID-19 epidemic.
06/09/2020	Joint conference of the GMDS & CEN-IBS 2020, Berlin, Germany. Causal inference methods in drug development after the ICH E9 addendum (jointly organized with Giusi Moffa, Björn Bornkamp). Cancelled because of COVID-19 epidemic.
29/06/2020	Joint seminar of the Basel Biometrics Section and EFSPI, Basel, Switzerland. Estimands addendum is final: feeling the change? (jointly organized with Evgeny Degtyarev, Bibiana Blatna, Marie-Laure Casadebaig, Lynda Grinsted, Lorenzo Guizzaro, Wolfgang Kothny, Giusi Moffa, Hans-Jochen Weber).
01/11/2019	Seminar of the Basel Biometrics Section, Basel, Switzerland. <i>Predictive modelling, machine learning and causality (jointly organized with Laurent Essioux, Dominik Heinzmann, Marcel Wolbers).</i>
31/07/2019	Joint Statistical Meetings, Denver, US. Estimand Framework and Its Impact on Drug Development in Oncology (jointly organized with Evgeny Degtyarev).
10/05/2019	Spring seminar of the Basel Biometrics Section, Basel, Switzerland. External controls - what do we need and how far can we go? (jointly organized with Hans Ulrich Burger, Dominik Heinzmann, Simon Wandel).
18/10/2018	Roche Early Development Research and Diagnostics Summit, Munich, Germany. Sta-

Trunzer).

tistical Know-How for Innovative Clinical Concepts (jointly organized with Kerstin

- 26/06/2018 Seminar of the Basel Biometrics Section, Basel, Switzerland. RCTs, personalized medicine, and surrogacy (jointly organized with Dietrich Knoerzer).
- 20/03/2018 Seminar of the Basel Biometrics Section, Basel, Switzerland. Competing Risks and Multistate Models (jointly organized with Dietrich Knoerzer, Amanda Ross, Marc Vandemeulebroecke, Simon Wandel, Marcel Wolbers).
- 13/09/2017 Roche European Biostatistics Conference, Welwyn, UK. Network Meta Analysis current challenges and the NICE perspective.
- 23/08/2017 Conference of the Central European Network of the International Biometric Society, Vienna, Austria. The assessment of probability of success for clinical trials (jointly organized with Hans Ulrich Burger and Marcel Wolbers).
- 18/06/2015 Joint Meeting of the International Biometric Society Austro-Swiss and Italian Regions, Milan, Italy. Adaptive clinical trials with subpopulation selection (jointly organized with Hans Ulrich Burger and Dominik Heinzmann).

Podcasts:

17/11/2020 The effective statistician podcast. A deep dive into principal stratification and causal inference (podcast jointly with Björn Bornkamp).

INVITED PRESENTATIONS:

- 2021 Center for Drug Evaluation Biostatistics Symposium, Beijing, China. *Estimands in oncology (virtual event)*.
- 29/04/2021 PSI One-Day Meeting: Non-proportional hazards and applications in immunooncology. Planning a Phase 3 trial with time-to-event endpoint, a cure proportion, and a futility interim analysis using response (virtual event).
- 17/03/2021 DIA Europe 2021, Basel, Switzerland. Stop the abuse: A plea for a more principled approach to the analysis of adverse events? (virtual event).
- 11/02/2021 Virtual Regulator Pharma Industry Forum: Statistical considerations in oncology clinical trials in the COVID-19 era, organized jointly by the American Statistical Association Biopharmaceutical Section, LUNGevity foundation, and the Oncology Center of Excellence, US FDA. How can the estimand framework support Decentralized Trials? (virtual event).
- 09/12/2020 Seminar, Vienna Biometric Section. Use of multistate models to improve decision-making in clinical trials (virtual event).
- 27/11/2020 Meeting of the Working Group *Pharmaceutical Research* of the German Region of the IBS (virtual event, talk together with Hannes Buchner). *Estimands update: Summary of world-wide authority interaction*.
- 21/10/2020 University of Basel, Basel. Use of multistate models to improve decision-making in clinical trials (virtual event).
- 11/06/2020 PSI conference webinar. Impact of COVID-19 to estimands (virtual event).
- 21/05/2020 Virtual panel discussion organized by Cytel. Estimands in oncology.
- 28/02/2020 University of Zurich / ETH applied statistics seminar, Zurich. Use of multistate models to improve decision-making in clinical trials.
- 25/02/2020 Joint workshop Swissmedic / swissethics "Workshop Complex Clinical Trials", Bern. A statistician's view on complex innovative designs.

- 14/11/2019 MRC Biostatistics Unit, Cambridge, UK. Use of multistate models to jointly model progression-free and overall survival and improve decision-making in clinical trials.
- 16/10/2019 Clinical Trials Europe, Basel, Switzerland. Implications of the ICH E9 estimand addendum on how we develop, run, and analyze clinical trials.
- 10/09/2019 Conference of the Austro-Swiss Region of the IBS, Lausanne, Switzerland. Before going BIG seize opportunities for small data: use of multistate models to improve decision-making and effect quantification in clinical trials.
- 04/07/2019 PSI webinar. rpact R Package for Adaptive Clinical Trials.
- 27/06/2019 Shanghai Biostatistics Forum, Shanghai, China. Multistate models to improve decision-making and effect quantification in clinical trials.
- 23/05/2019 Bayesian Biostatistics Conference (bayes-pharma), Lyon, France. Bayesian Predictive Power: Theory, challenges in implementation, and perspectives.
- 10/05/2019 Spring seminar of the Basel Biometric Section, Basel, Switzerland. External controls in drug development (with Hans Ulrich Burger).
- 02/04/2019 SMi conference on adaptive clinical trials, London, UK. MIRROS: Phase 3 trial with time-to-event endpoint, cure proportion, and futility interim analysis using response.
- 22/11/2018 Statistics seminar, University of Bochum, Germany. Univariate log-concave density estimation and more efficient treatment effect estimation in pre-specified subgroups displayed in forest plots for time-to-event outcomes.
- 23/10/2018 Oncology workshop, University of Heidelberg, Germany. MIRROS: Planning a Phase 3 trial with time-to-event endpoint, a cure proportion, and a futility interim analysis using response.
- 18/10/2018 Roche RxDx summit, Munich, Germany. Randomization and External Controls When to Use What in a Drug Development Landscape.
- 10/09/2018 Modeling and Simulation seminar, Basel, Switzerland. Immortal bias you live longer if you cannot die.
- 21/06/2018 Biostatistics group Boehringer-Ingelheim, Biberach, Germany. Overall survival prediction conditional on post-randomization events: multistate models, landmark analyses, and others.
- 13/02/2018 Special Colloquia Epidemiology, Biostatistics, and Prevention Institute, University of Zurich, Zurich, Switzerland. Estimands and the ICH E9 draft addendum.
- 24/11/2017 Meeting of the Working Group *Pharmaceutical Research* of the German Region of the IBS, Freiburg, Germany. *Treatment effect measures for time-to-event endpoints estimands, analysis strategies, and beyond.*
- 03/11/2017 Adaptive Clinical Trials Summit, Berlin, Germany (conference was cancelled). MIR-ROS a phase III trial with overall survival primary endpoint, a cure proportion, and a futility interim analysis using response and event-free survival.
- 04/10/2017 2nd EFSPI Regulatory Statistics Workshop, Basel, Switzerland. Construction of an Estimand in a Clinical Trial on Progressive Multiple Sclerosis.
- 31/08/2017 Joint Meeting of the International Biometric Society Austro-Swiss, German, and Polish Region, Vienna, Austria. Evolvement of assurance over the lifecycle of several Phase 3 trials in a large oncology clinical development program.
- 13/06/2017 Workshop on Innovation in Oncology Clinical Trial Design, organized by the Cancer Drug Development Forum (CDDF), Frankfurt. Treatment effect measures for time-to-event endpoints Estimands and beyond.
- 13/03/2017 Seminar, Basel Biometric Section of the IBS, Basel. Comparison of clinical development plans for a confirmatory trial with subpopulation selection.
- 12/12/2016 Statistics Seminar, Institute for Medical Biometry, University of Heidelberg, Heidelberg. Bayesian Predictive Power: update after a blinded interim analysis and choice of update after a blinded interim analysis and choice of prior.

- 14/11/2016 European Statistical Forum, Berlin. Estimands for time to event endpoints.
- 10/11/2016 Statistics Seminar, Institute for Social and Preventive Medicine, University of Lausanne, Lausanne. Bayesian Predictive Power: update after a blinded interim analysis and choice of prior.
- 12/09/2016 1st EFSPI Regulatory Statistics Workshop, Basel. Estimands for time to event endpoints in oncology and beyond (delivered by Uli Burger).
- 24/05/2016 PSI conference, Berlin. Time to think about estimands for time-to-event endpoints? A few examples (delivered by Uli Burger).
- 28/04/2016 Seminar, Basel Biometric Section of the IBS, Basel. Event projection: quantify uncertainty and manage expectations of broader teams.
- 02/03/2016 Statistics Seminar, University of Ulm, Ulm. Bayesian Predictive Power: Choice of Prior and some Recommendations for its Use as Probability of Success in Drug Development.
- 20/11/2015 3rd BIMIT (Verbundprojekt "Biostatistische Methoden zur effizienten Evaluation von Individualisierten Therapien") workshop, Göttingen. A Weibull Regression Model for a Time-to-Event Endpoint with an Interval-Censored Covariate and its Application in Assessing Prentice's Criteria for Surrogacy.
- 27/10/2015 Seminar, Basel Biometric Section of the IBS, Basel. Bayesian Predictive power: the bathtub phenomenon.
- 18/06/2015 Joint Meeting of the International Biometric Society Austro-Swiss and Italian Regions, Milan, Italy. Comparison of clinical development plans for a confirmatory trial with subpopulation selection.
- 17/04/2015 Seminar, Institute for Mathematical Statistics and Actuarial Science, University of Bern, Switzerland. Bayesian predictive power: update after a blinded interim & fallacies.
- 20/11/2014 2nd BIMIT (Verbundprojekt "Biostatistische Methoden zur effizienten Evaluation von Individualisierten Therapien") workshop, Bremen. How good is your biomarker? Comparison of development plans for confirmatory biomarker enrichment.
- 11/11/2014 Joint DIA/AEMPS Statistics Workshop, Barcelona. How good is your biomarker? Comparison of development plans for confirmatory biomarker enrichment.
- 18/09/2014 2nd Symposium for the RxDx Generation, Roche, Penzberg. How statistics can contribute to innovative trials.
- 27/03/2014 University of Zurich / ETH applied statistics seminar, Zurich. Update Bayesian predictive power after a blinded interim analysis.
- 12/05/2010 Research Section Meeting Royal Statistical Society, London. Proposal of the vote of thanks in discussion of Cule, M., Samworth, R., and Stewart, M.: Maximum likelihood estimation of a multidimensional logconcave density.
- 26/01/2010 Workshop "Statistical Issues in Prediction: What can be Learned for Individualized Predictive Medicine?", Oberwolfach, Germany. Score regression: a new approach to assess calibration of continuous probabilistic predictions.
- 12/01/2010 Seminar, Basel Biometric Section of the IBS, Basel. Ordered monotone regression.
- 11/02/2009 Department of Neurology and Neurological Sciences, Stanford University School of Medicine, Palo Alto, CA, USA. Regularized regression models in R.
- $\begin{array}{ll} 17/01/2008 & \text{Seminar, Basel Biometric Section of the IBS, Basel.} \\ A \ general \ criterion \ for \ multiscale \ inference. \end{array}$
- $18/12/2007 \qquad \text{Seminar, Institute for Stochastics, University of Karlsruhe, Germany.} \\ Nonparametric \ Estimation \ of \ Log-Concave \ Densities.}$
- 28/09/2007 Seminar, Institute for Mathematical Statistics and Actuarial Science, University of Bern, Switzerland. A general criterion for multiscale inference.

- 13/09/2007 Basel Institute for Clinical Epidemiology, University of Basel, Switzerland. Predicting Alzheimer from proteomic blood markers.
- 31/07/2007 Seminar, Statistics Department, Stanford University, United States.
 - Max-domain of attraction for log-concave densities and smooth tail index estimation.
- 11/11/2006 Workshop "Qualitative Assumptions and Regularization in High-Dimensional Statistics", Oberwolfach, Germany. The log-concave density estimator as a smoother.
- $23/08/2005 \qquad \text{Seminar, Statistics Department, Stanford University, United States.} \\ Log-concave \ density \ estimation.$

CONTRIBUTED CONFERENCE PRESENTATIONS:

- 04/06/2019 PSI annual conference, London, UK. Estimand framework in Oncology drug development impact and opportunities.
- 19/03/2019 Annual Meeting of the International Biometric Society, German Region, Munich, Germany. Estimand framework in Oncology drug development impact and opportunities (talk delivered by Björn Bornkamp).
- 17/10/2018 Roche Global Biostatistics Conference, Madrid, Spain. Assess Common Surrogate Endpoints in Lymphoma using a Multistate Model.
- 04/10/2018 Workshop on Adaptive Designs and Multiple Testing Procedures, Bremen, Germany. More efficient treatment effect estimation in pre-specified subgroups displayed in forest plots for time-to-event outcomes.
- 28/03/2018 Annual Meeting of the International Biometric Society, German Region, Frankfurt, Germany. The Estimand Framework Applied to Time-to-event Endpoints.
- 12/07/2017 Annual Conference of the International Society for Clinical Biostatistics, Vigo, Spain. Joint modelling of progression-free and overall survival.
- 23/08/2016 Annual Conference of the International Society for Clinical Biostatistics, Birmingham, Great Britain. Bayesian Predictive Power: Choice of Prior and some implications.
- 24/05/2016 PSI annual conference, Berlin, Germany. Bayesian Predictive Power: Choice of Prior and some Recommendations for its Use as Probability of Success in Drug Development (delivered by Markus Abt).
- 16/06/2015 Joint Meeting of the International Biometric Society Austro-Swiss and Italian Regions, Milan, Italy. Evaluation of possible designs for a three-arm clinical trial: Comparing a closed-testing design to potential alternatives.
- 20/05/2015 Roche Global Biostatistics Conference, San Francisco, United States. Evaluation of possible designs for a three-arm clinical trial: Comparing the CLL11 design to potential alternative designs.
- 28/08/2014 Annual Conference of the International Society for Clinical Biostatistics, Vienna, Austria. Weibull Regression for a Right-Censored Endpoint with a Censored Covariate.
- 02/07/2014 Bayesian Biostatistics 2014 Satellite conference of the International Biometric Conference, Zurich, Switzerland. *Update Bayesian predictive power after a blinded interim analysis*.
- 23/10/2013 Update Bayesian Predictive Power after a blinded interim analysis, Roche Global Biostatistics Conference, Brighton, United Kingdom.
- 13/09/2011 Conference of the Central European Network of the International Biometric Society (CEN 2011), Zurich, Switzerland. A smooth ROC curve estimator based on log-concave density estimates.
- 21/06/2011 Methods in Meta Analysis Meeting, London, UK. Selection models with monotone weight functions in meta analysis.
- 03/08/2010 Joint Statistical Meetings, Vancouver, Canada. Ordered Monotone Regression.

- 02/03/2010 German Open Conference on Probability and Stochastics, Leipzig, Germany. Ordered $Monotone\ Regression.$
- 12/03/2008 Conference of the Central European Network of the International Biometric Society (Lifestat 2008), Munich, Germany. On a new approach to regression models with ordinal explanatory variables.
- 11/09/2007 ROeS Seminar 2007, Bern, Switzerland.

 On a new approach to regression with ordered explanatory variables.
- 15/03/2006 German Open Conference on Probability and Stochastics, Frankfurt, Germany. Smoothed semi-parametric tail index estimation and max-domain of attraction for log-concave densities.
- 27/07/2005 European Meetings of Statisticians, Oslo, Norway. Log-concave density estimation.
- 19/07/2005 European Young Statisticians Training Camp, Oslo, Norway. Log-concave density estimation and bump hunting.
- 26/03/2004 German Open Conference on Probability and Stochastics, Karlsruhe, Germany. Logconcave density estimation and uniform rate of convergence.
- 06/08/2003 Joint Statistical Meetings, San Francisco, United States. Computing maximum likelihood estimators of log-concave densities.

Internal methodological presentations:

- 15/06/2020 Complex innovative designs: adaptive, basket, umbrella and beyond (presented to all Roche statisticians globally in virtual seminars).
- 13/08/2019 External controls in drug development (Roche Oncology Forum, Basel & Welwyn).
- 27/06/2019 MIRROS: Planning a Phase 3 trial with time-to-event endpoint, a cure proportion, and a futility interim analysis using response (Roche Biostatistics Department, Shanghai).
- 18/03/2019 To explain or to predict what is the difference? And how to plan a prediction model? (Biostatistics workshop, Department of Biostatistics, Basel).
- 27/02/2019 To be fast or to be sure? Trade-offs in drug development (Roche Early Development and Research (pRED) Science@Site Lecture Series, Basel).
- 30/01/2019 MIRROS: Planning a Phase 3 trial with time-to-event endpoint, a cure proportion, and a futility interim analysis using response (Roche Biostatistics Department, Welwyn).
- 16/07/2018 Extract more information from a clinical trial than just Kaplan-Meier estimates of the primary endpoint: a case study in multistate modeling (Biostatistics workshop, Department of Biostatistics, Basel).
- 09/10/2017 Quantification of follow-up for a time-to-event endpoint (Biostatistics workshop, Department of Biostatistics, Basel).
- 20/09/2017 Joint modelling of progression-free and overall survival (Seminar, Roche Germany Biostatistics and Epidemiology Group, Grenzach).
- 13/09/2017 Estimands a refinement of ITT (jointly with Chris Harbron, Roche Basel Welwyn Shanghai Biostatistics Conference, Welwyn).
- 23/05/2017 Estimands current ICH E9 working group proposal (jointly with Chris Harbron, Genentech North America Biostatistics Seminar, South San Francisco).
- 19/12/2016 Estimands do you know what you are estimating? (Roche HTA group, Basel).
- 24/11/2016 Compare Phase 3 with futility interim to randomized Phase 2 + Phase 3 and single-arm Phase 2 + Phase 3 (Roche Statistics Workshop, Welwyn).
- 25/09/2016 Immortal time bias and post-randomization variables (jointly with Marcel Wolbers, Roche Statistics Workshop, Basel).

11/05/2016	Bayesian Predictive Power - Choice of Prior (Genentech North-American Biostatistics
	Forum, South San Francisco).

- 15/10/2015 Estimands do you know what you are estimating? (Roche Basel & Welwyn Joint Biostatistics Seminar, Welwyn).
- 29/09/2015 Hierarchical testing of a secondary endpoint in a group-sequential design (Roche Statistics Workshop, Welwyn).
- 17/08/2015 Bayesian Predictive power: the bathtub phenomenon (Roche Statistics Workshop, Basel).
- 16/02/2015 Hierarchical testing of a secondary endpoint in a group-sequential design (Roche Statistics Workshop, Basel).
- 20/08/2014 Estimation of a survival curve beyond where we have data, with application to event tracking for time-to-event outcomes (Health Economics Department, Roche Basel).
- 11/08/2014 Event tracking for time-to-event outcomes (Roche Asia Pacific Biostatistics Workshop).
- 24/07/2014 Statistical MythBusters (Roche Oncology Forum, Basel & Welwyn).
- 16/06/2014 Event tracking for time-to-event outcomes (Roche Statistics Workshop, Basel).
- 17/12/2013 Immortal bias or why it is a bad idea to plot a time-to-event endpoint by response category (Roche Statistics & Oncology Forum, Shanghai).
- 06/11/2013 Some examples for R and Sweave applications (Roche Statistical Programming Workshop, Basel).
- 02/09/2013 Immortal bias or why it is a bad idea to plot a time-to-event endpoint by response category (Roche Biostatistics Basel/Welwyn/Shanghai Meeting, Basel).
- 04/02/2013 Probability of technical success: Conditional Power, Bayesian Predictive Power, or Bayesian Updating? (Roche Biostatistics Basel/Welwyn/Shanghai Meeting, Basel).
- 17/12/2012 Writing R packages and use of Sweave (Roche Statistics Workshop, Basel).
- 30/11/2012 Probability of technical success two ways of looking at it (Roche pRED Meeting, Basel/Nutley).
- 19/11/2012 Unbiased estimation of a proportion after a 2-stage trial (Roche Statistics Workshop, Basel).
- 12/07/2012 A new smooth ROC curve estimate based on log-concave densities (Roche Biostat Biomarker Community Meeting, Basel).
- 27/01/2011 Categorization of continuous covariates (Zurich).
- 03/12/2009 p-values in high-dimensional regression (Zurich).
- 04/06/2009 Estimation and computation of the median for right-censored data (Zurich).
- 12/01/2009 Consulting and reproducible research (Zurich).
- 06/11/2008 Exact logistic regression (Zurich).
- 06/03/2008 L_1 and Least angle regression (Zurich).
- 06/12/2007 On a new approach to regression with ordinary explanatory variables (Zurich).
- 25/01/2006 Semi-parametric tail index estimation and max-domain of attraction for log-concave densities (Bern).
- 04/05/2005 Local asymptotic normality and Le Cam's third lemma (Bern).
- 11/01/2005 Penalized estimators (Bern).
- 01/12/2004 Asymptotics for Lasso-Type Estimators (Bern).
- 28/04/2004 Estimation of a Proportion in Group Sequential Trials (Bern).
- 26/11/2003 Density Estimation under Qualitative Assumptions (Bern).
- 07/01/2003 Convex Programming (Bern).