

# Presentations

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## ORGANIZATION OF SEMINARS 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. *How can statistics help to disrupt drug development?* (jointly organized with Marcel Wolbers).
- 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 Grinstead, Lorenzo Guizzaro, Wolfgang Kothny, Giusi Moffa, Hans-Jochen Weber).
- 01/11/2019 Seminar of the Basel Biometrics Section, Basel, Switzerland. *Predictive modelling, machine learning and causality* (jointly organized with Laurent Essioux, Dominik Heinzmann, Marcel Wolbers).
- 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. *Statistical Know-How for Innovative Clinical Concepts* (jointly organized with Kerstin Trunzer).

- 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).*
- 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, talk together with Tim Friede).*
- 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). *MIRROS - 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. *Evolution 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*.
- 17/01/2008 Seminar, Basel Biometric Section of the IBS, Basel. *A general criterion for multiscale inference*.
- 18/12/2007 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 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. <i>On a new approach to regression with ordered explanatory variables.</i>
15/03/2006	German Open Conference on Probability and Stochastics, Frankfurt, Germany. <i>Smoothed semi-parametric tail index estimation and max-domain of attraction for log-concave densities.</i>
27/07/2005	European Meetings of Statisticians, Oslo, Norway. <i>Log-concave density estimation.</i>
19/07/2005	European Young Statisticians Training Camp, Oslo, Norway. <i>Log-concave density estimation and bump hunting.</i>
26/03/2004	German Open Conference on Probability and Stochastics, Karlsruhe, Germany. <i>Log-concave density estimation and uniform rate of convergence.</i>
06/08/2003	Joint Statistical Meetings, San Francisco, United States. <i>Computing maximum likelihood estimators of log-concave densities.</i>

#### 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).