Kelly Van Lancker

Education and Training

2022—present **Postdoctoral training**, *Department of Applied Mathematics, Computer Science and Statistics*, Ghent University, Ghent, Belgium.

Advisor: Prof. Stijn Vansteelandt

2021–2022 **Postdoctoral training**, *Department of Biostatistics*, Johns Hopkins Bloomberg School of Public Health, Baltimore, USA.

Advisor: Prof. Michael Rosenblum

2017–2021 **PhD candidate in Statistical Data Analysis**, *Department of Applied Mathematics*, *Computer Science and Statistics*, Ghent University, Ghent, Belgium.

Advisors: Prof. Stijn Vansteelandt and Dr. An Vandebosch

Dissertation: Faster and more efficient decision-making in randomized experiments via prediction of the treatment effect based on patient characteristics, biomarkers and interim read-outs.

2015–2017 Master of Science in Mathematics, Ghent University, Ghent, Belgium.

Advisor: Dr. An Vandebosch (Janssen)

Thesis: Evaluating futility of the clinical endpoint using early read-outs: methods and application

to a case study

2012–2015 Bachelor of Science in Mathematics, Ghent University, Ghent, Belgium.

Experience

February- Research visit to Prof. Michael Rosenblum, Johns Hopkins University, Baltimore, March 2023 U.S.A..

Extending our work to combine covariate adjustment with group sequential designs for one hypothesis to multiple hypotheses.

2017-2021 **Researcher in Statistical Modeling and Methodology Group**, *Janssen*, Beerse, Belgium.

During my PhD I was spending 40% of my time at Janssen under the supervision of An Vandebosch.

June 2019 **Research visit to Prof. Werner Brannath**, *University of Bremen*, Bremen, Germany. Fruitful discussions on the use of baseline covariates and early read-outs in adaptive designs, which have lead to impactful improvements to one of our papers. Talk for the statistics department.

2016 Internship in Statistical Modeling and Methodology Group, *Janssen*, Beerse, Belgium.

Running simulations in R to test the performance of a new method to incorporate an early read-out of a binary endpoint in an interim analysis. Developing software in the form of an R package for this method.

2015-2016 **Teaching assistant (as job student)**, *Ghent Univeristy*, Ghent, Belgium.

Providing support for the course "Statistics and Pharmaceutical Data Analysis" in the second year of the Bachelor's degree in Pharmaceutical Sciences.

Awards and Prizes

- 2022 Junior Researcher Travel Grant to attend the American Causal Inference Conference, Berkeley, USA.
- 2021 Quetelet Prize from the International Biometric Society for outstanding PhD thesis in the field of Biometrics, *Belgium*.
- 2020 Finalist PhD Innovation Café, Ghent University, Belgium.
- 2019 Runner-up for best presentation by a young researcher at the European causal inference meeting, *Bremen, Germany*.
- 2018 Abstract selected for special presentation with invited discussant at the 26th Annual Meeting of the Royal Statistical Society of Belgium, *Ovafit, Belgium*.

Peer-Reviewed Publications

Kelly Van Lancker, Sergey Tarima, Jonathan Bartlett, Madeline Bauer, Bharani Bharani-Dharan, Frank Bretz, Nancy Flournoy, Hege Michiels, Camila Olarte Parra, James L Rosenberger & Suzie Cro. "Rejoinder: Estimands and their Estimators for Clinical Trials Impacted by the COVID-19 Pandemic: A Report from the NISS Ingram Olkin Forum Series on Unplanned Clinical Trial Disruptions". *Statistics in Biopharmaceutical Research*, 2022. DOI: 10.1080/19466315.2022.2162958.

Kelly Van Lancker, Tat-Thang Vo & Mouna Akacha. "Estimands in heath technology assessment: a causal inference perspective". *Statistics in Medicine*, 2022. https://doi.org/10.1002/sim.9539.

Stijn Vansteelandt, Oliver Dukes, **Kelly Van Lancker** & Torben Martinussen. "Assumption-lean Cox regression". *Journal of the American Statistical Association*, 2022. DOI: 10.1080/01621459.2022.2126362.

Kelly Van Lancker, Sergey Tarima, Jonathan Bartlett, Madeline Bauer, Bharani Bharani-Dharan, Frank Bretz, Nancy Flournoy, Hege Michiels, Camila Olarte Parra, James L Rosenberger & Suzie Cro. "Estimands and their Estimators for Clinical Trials Impacted by the COVID-19 Pandemic: A Report from the NISS Ingram Olkin Forum Series on Unplanned Clinical Trial Disruptions". *Statistics in Biopharmaceutical Research*, 2022. DOI: 10.1080/19466315.2022.2094459.

Kelly Van Lancker, An Vandebosch & Stijn Vansteelandt. "Efficient, Doubly Robust Estimation of the Effect of Dose Switching for Switchers in a Randomised Clinical Trial". *Biometrical Journal*, 2021. https://doi.org/10.1002/bimj.202000269.

Kelly Van Lancker, Oliver Dukes & Stijn Vansteelandt. "Principled Selection of Baseline Covariates to Account for Censoring in Randomized Trials with a Survival Endpoint". *Statistics in Medicine*, 2021. https://doi.org/10.1002/sim.9017.

Oliver Dukes, **Kelly Van Lancker**, Kaspar Rufibach, Björn Bornkamp, Dominik Heinzmann & Marcel Wolbers. "Identification of the Principal Stratum Effect in Patients Who Would Comply If Treated". *Statistics in Biopharmaceutical Research*, 2021. doi: 10.1080/19466315.2021.1872697.

Cornelia Ursula Kunz, Silke Jörgens, Frank Bretz, Nigel Stallard, **Kelly Van Lancker**, Dong Xi, Sarah Zohar, Christoph Gerlinger & Tim Friede. "Clinical Trials Impacted by the COVID-19 Pandemic: Adaptive Designs to the Rescue?". *Statistics in Biopharmaceutical Research*, 2020, 12: 461-477. doi:10.1080/19466315.2020.1799857.

Kelly Van Lancker, An Vandebosch & Stijn Vansteelandt. "Improving interim decisions in randomized trials by exploiting information on short-term endpoints and prognostic baseline covariates". *Pharmaceutical Statistics*, 2020, 19: 583–601. doi:10.1002/pst.2014.

Kelly Van Lancker, An Vandebosch, Stijn Vansteelandt & Filip De Ridder. "Evaluating futility of a binary clinical endpoint using early read-outs". *Statistics in Medicine*, 2019, 38: 5361–5375. doi:10.1002/sim.8366.

Under Review

Kelly Van Lancker, Oliver Dukes & Stijn Vansteelandt. "Ensuring valid inference for conditional causal hazard ratios after variable selection".

Kelly Van Lancker, Joshua Betz & Michael Rosenblum. "Combining Covariate Adjustment with Group Sequential, Information Adaptive Designs to Improve Randomized Trial Efficiency".

Silvia Calderazzo, Sergey Tarima, Carissa Reid, Nancy Flournoy, Tim Friede, Nancy Geller, James Rosenberger, Nigel Stallard, Moreno Ursino, Marc Vandemeulebroecke, **Kelly Van Lancker** & Sarah Zohar "Clinical trials impacted by COVID-19: Coping with Information Loss and the Use of Auxiliary Sources of Data".

Work in Progress

Kelly Van Lancker, Oliver Dukes & Frank Bretz "Is Covariate Adjustment in Randomized Trials Worth the Effort?"

Kelly Van Lancker, Ivan Diáz & Stijn Vansteelandt "Valid inference after variable selection for covariate adjusted estimators?"

Invited Talks

- September Covariate Adjustment in Randomized Controlled Trials, CEN2023 Conference, 2023 Basel, Switserland.
- March 2023 Covariate Adjustment in Group Sequential Trials with Multiple Hypotheses, *ENAR*, Nashville, U.S.A..
 - November The hypothetical estimand and its potential estimators in clinical trials impacted by COVID-19, *DIA Innovative Trial Design Conference*, Virginia, U.S.A., Joined online.
 - May 2022 Combining Covariate Adjustment with Group Sequential and Information Adaptive Designs to Improve Randomized Trial Efficiency, Annual Meeting of the Society for Clinical Trials, San Diego, U.S.A..
- October 2021 **The hypothetical estimand and its potential estimators in clinical trials impacted by COVID-19**, *Design and Analysis of Experiments Conference Series in North America*, took place online.
 - September Improving interim decisions in randomized trials by exploiting information on short-term outcomes and prognostic baseline covariates, XXIInd Conference of the Austro-Swiss Region (ROeS) of the International Biometric Society, Salzburg, hybrid.
- August 2021 Clinical trials impacted by the COVID-19 pandemic: Adaptive designs to the rescue?, *Joint Statistical Meeting*, Seattle, U.S.A, took place online.

- June 2021 **Improving efficiency in both interim and final analyses**, *Webinar on Targeted Learning*, Ghent, Belgium, took place online.
- May 2021 Ensuring valid inference for conditional causal hazard ratios after variable selection, *Lifetime Data Science conference*, North Carolina, U.S.A, cancelled due to COVID-19.
- March 2021 Clinical trials impacted by the COVID-19 pandemic: Adaptive designs to the rescue?, *ENAR*, Baltimore, U.S.A, took place online.
- March 2021 Efficient, doubly robust estimation of the effect of dose switching for switchers in a randomised clinical trial, German Biometric Colloquium, Münster, Germany, took palce online.
- August 2020 Honest Inference for Conditional Causal Hazard Ratios After Selection of High-Dimensional Confounders, *Joint Statistical Meeting*, Philadelphia, U.S.A, took place online.

Invited Seminars

- May 2023 Valid Inference for Conditional Causal Hazard Ratios After Variable Selection, Probability and Statistics Seminar at University of Luxembourg, Esch-sur-Alzette, Luxembourg.
- February **Covariate Adjustment in Randomized Controlled Trials**, *Winter School Design* 2023 and Analysis of Clinical Trials organized by Ghent University, Ghent, Belgium.
- February Improving the Efficiency of of Interim Analyses by Incorporating Short-Term 2023 Outcomes and Baseline Covariates, Winter School Design and Analysis of Clinical Trials organized by Ghent University, Ghent, Belgium.
- December **Discussion on hypothetical strategies: a causal inference perspective**, 2022 *BBS/EFSPI*, virtual workshop "Addressing intercurrent events: Treatment policy and hypothetical strategies".
- November Covariate Adjustment in Randomized Controlled Trials, Novartis, Basel, 2022 Switzerland.
- June 2022 Combining Covariate Adjustment with Group Sequential and Information Adaptive Designs to Improve Randomized Trial Efficiency, Google Statistics journal Club, California, U.S.A., took place online.
- June 2022 Combining Covariate Adjustment with Group Sequential and Information Adaptive Designs to Improve Randomized Trial Efficiency, National Institute of Allergy and Infectious Diseases, Rockville, U.S.A., took place online.
- June 2022 Combining Covariate Adjustment with Group Sequential and Information Adaptive Designs to Improve Randomized Trial Efficiency, National Cancer Institute, Rockville, U.S.A., took place online.
- April 2022 Combining Covariate Adjustment with Group Sequential and Information Adaptive Designs to Improve Randomized Trial Efficiency, *University of Pennsylvania*, Philadelphia, U.S.A., took place online.
- March 2022 Combining Covariate Adjustment with Group Sequential and Information Adaptive Designs to Improve Randomized Trial Efficiency, *Novartis*, Basel, Switzerland, took place online.

- January 2022 Combining Covariate Adjustment with Group Sequential and Information Adaptive Designs to Improve Randomized Trial Efficiency, Emory University, Atlanta, U.S.A., took place online.
 - November Clinical trials impacted by the COVID-19 pandemic: Adaptive designs to the 2021 rescue?, WebENAR: Estimands, Estimators, and Estimates, took place online.
 - June 2021 **Covariate Adjustment in Randomized Trials**, *Oncology estimand working group*, took place online.
 - June 2021 The hypothetical estimand and its potential estimators in clinical trials impacted by COVID-19, Basel Biometrics Section webinar, took place online.
 - February Methodological Challenges of Clinical Trials Impacted by the COVID-19 Pan-2021 demic, Free University of Berlin, Berlin, Germany, took place online.
- October 2020 Honest Inference for Conditional Causal Hazard Ratios After Selection of High-Dimensional Confounders, Johns Hopkins Bloomberg School of Public Health, Baltimore, U.S.A, took place online.
 - Sept. 2020 Efficient, doubly robust estimation of the effect of dose switching for switchers in a randomised clinical trial, Basel Biometrics Section webinar, took place online.
- August 2020 Improving interim decisions in randomized trials by exploiting information on short-term outcomes and prognostic baseline covariates, *Novartis*, Basel, Switzerland, took place online.
 - June 2019 Improving interim decisions in randomized trials by exploiting information on short-term outcomes and prognostic baseline covariates, *University of Bremen*, Bremen, Germany.

Other Presentations at Conferences and Workshops

- April 2023 Combining Covariate Adjustment with Group Sequential and Information Adaptive Designs to Improve Randomized Trial Efficiency, Adaptive Designs and Multiple Testing Procedures Workshop, Basel, Switzerland.
- August 2022 **The hypothetical estimand and its potential estimators in clinical trials impacted by COVID-19**, *Joint Statistical Meeting*, Washington D.C., U.S.A..
 - May 2022 Combining Covariate Adjustment with Group Sequential and Information Adaptive Designs to Improve Randomized Trial Efficiency, American Causal Inference Conference, Berkeley, U.S.A..
- March 2022 Combining Covariate Adjustment with Group Sequential and Information Adaptive Designs to Improve Randomized Trial Efficiency, *ENAR*, Houston, U.S.A., hybrid.
 - April 2020 Ensuring valid inference for the effect of a treatment on a time-to-event endpoint in Cox models with variable selection, European Causal Inference Meeting, Oslo, Norway, took place online.
- October 2019 **Efficient, doubly robust estimation of the effect of dose switching for switchers in a randomised clinical trial**, 27th Annual Meeting of the Royal Statistical Society of Belgium, Sint-Truiden, Belgium.

- August 2019 Efficient, doubly robust estimation of the effect of dose switching for switchers in a randomised clinical trial, The 6th International Symposium on Biopharmaceutical Statistics, Kyoto, Japan.
- August 2019 Improving interim decisions in randomized trials by exploiting information on short-term outcomes and prognostic baseline covariates, 40th Annual Conference of the International Society for Clinical Biostatistics, Leuven, Belgium.
- March 2019 Efficient, doubly robust estimation of the effect of dose switching for switchers in a randomised clinical trial, European Causal Inference Meeting, Bremen, Germany.
- October 2018 Improving interim decisions in randomized trials by exploiting information on short-term outcomes and prognostic baseline covariates, Annual Workshop of the joint working group on "Adaptive Designs and Multiple Testing Procedures", Bremen, Germany.
- October 2018 Improving interim decisions in randomized trials by exploiting information on short-term outcomes and prognostic baseline covariates, 26th Annual Meeting of the Royal Statistical Society of Belgium, Ovifat, Belgium.

Professional Activities

- September Short-course lecturer at the ASA Biopharmaceutical Section Regulatorylndustry Statistics Workshop "Implementing the estimand framework in RCTs: application of causal inference approaches", Rockville, U.S.A. Co-lecturers: Mouna Akacha, Tianmeng Lyu, Jiarui Lu and Kaspar Rufibach
- September Invited session organizer at the CEN2023 conference "A causal inference 2023 perspective on estimands in clinical trials.", Basel, Switserland.
- September Short-course organizer at the CEN2023 conference "Improving Precision and Power in Randomized Trials by Leveraging Baseline Variables", Basel, Switzerland. Co-lecturers: Josh Betz and Michael Rosenblum.
- June 2023 Short-course organizer at the annual PSI conference "Improving Precision and Power in Randomized Trials by Leveraging Baseline Variables", Londong, U.K.. Co-lecturers: Josh Betz and Michael Rosenblum.
- March 2023 Short-course organizer at ENAR "Improving Precision and Power in Randomized Trials by Leveraging Baseline Variables", Nashville, U.S.A.

 Co-lecturers: Josh Betz and Michael Rosenblum.
- September Short-course organizer at the ASA Biopharmaceutical Section Regulatorylndustry Statistics Workshop "Improving Precision and Power in Randomized
 Trials by Leveraging Baseline Variables", Rockville, U.S.A.
 Lecturers: Josh Betz and Michael Rosenblum. Unfortunately, I was not able to attend myself.
- September Invited session organizer at the ASA Biopharmaceutical Section Regulatorylndustry Statistics Workshop "When and how to use covariate adjustment to improve precision in randomized trials.", Rockville, U.S.A.
- August 2022 Topic-contributed session organizer at the Joint Statistical Meeting "The use of baseline covariates and early read-outs in adaptive and group sequential designs: worth the effort?", Washington D.C., U.S.A.

 Speakers: Michael Rosenblum, Nigel Stallard, Tim Friede, Kaspar Rufibach and Abigail Burdon.

May 2022 Short-course organizer at the Annual Meeting of Society for Clinical Trials "Improving Precision and Power in Randomized Trials by Leveraging Baseline Variables", San Diego, U.S.A.

Co-lecturers: Josh Betz and Michael Rosenblum.

May 2022 Invited session organizer at the Annual Meeting of Society for Clinical Trials "When and how to use covariate adjustment to improve precision in randomized trials.", San Diego, U.S.A.

Speakers: Mark van der Laan, Min Zhang and Kelly Van Lancker.

June 2021 Organization of Webinar "A gentle introduction to targeted learning in RCTs: what, why and how?", Ghent University, Ghent, Belgium.

To celebrate the end of my PhD, I organized a webinar on targeted learning. Speakers: Rhian Daniel, Oliver Dukes, Alex Luedtke and Stijn Vansteelandt. Discussants: Björn Bornkamp, Susan Gruber, Hana Lee, Frank Petavy and Jose Pinheiro.

2020-present Leading the NISS (National Institute of Statistical Sciences) working group on estimands for trials impacted by COVID-19.

The aim of such a group -with pioneering statisticians in pharma and academia- is to put together a paper outlining the questions raised at the NISS event on estimands for trials impacted by COVID-19 and to articulate avenues of research which could be pursued to address them

Editorial Activities

Reviewer at Biometrics, Biostatistics, Clinical Trials, Epidemiology, Journal of Causal Inference, Journal of the Royal Statistical Society: Series A, Journal of the Royal Statistical Society: Series B, Lifetime Data Analysis, Statistics in Biopharmaceutical Research, Statistics in Medicine, Statistical Methods in Medical Research, and Trials.

2023- Associate editor at Statistics in Biopharmaceutical Research.

Teaching

- 2022- Co-lecturer for **Statistics and Pharmaceutical Data Analysis**, Bachelor in Pharmaceutical Sciences, Ghent University.
- 2018-2019 Teaching assistant for **Survival Analysis**, M.Sc. Statistical Data Analysis and M.Sc. Mathematics, Ghent University.
- 2015-2021 Teaching assistant for **Statistics and Pharmaceutical Data Analysis**, Bachelor in Pharmaceutical Sciences, Ghent University.

Funding and Research grants

- 2023 Grant for a one month research visit to Johns Hopkins University (U.S.A.) from Research Foundation Flanders (FWO)
- 2021 Postdcotoral fellowship (three years) from Bijzonder Onderzoeksfonds (BOF)
- 2021 Fulbright U.S. Research Grant , Belgium-United States.
- 2021 Belgian American Educational Foundation Post-Doctoral Research Fellowship, Belgium-United States.
- 2017 Flanders Innovation and Entrepeneurship (VLAIO) Baekeland PhD grant, Belgium.

Languages

Dutch Native

English Fluent

French Intermediate

German Basic

Programming skills

R, SAS, SPSS, Latex, Java

Soft skills

Eager to learn, hard working, analytical thinking, enthousiastic, social, leadership

Interests

Pottery, hiking, plants, running, photography