Target Group

This is the tenth in a series of annual Biostatistics Summer schools in Strobl. The course will cover methodology developed within the meta-analytic and causal inference schools and will have an intermediate level of difficulty

Prerequisites

Participants should have some prior knowledge and experience in the following areas:

- Basic statistical theory and applications
- Basic knowledge of meta-analysis and their application
- Basic knowledge about Causal inference methods
- Clinical trials

It is helpful if participants also have experience using statistical software such as R or SAS for data analysis. Overall, the content covered will be applicable to researchers and professionals working in the field of clinical research and healthcare.

Time and Date

Tuesday 23 June until Friday 26 June 2026

- Please arrive on Tuesday by 14:00
- Course finishes Friday by 12:30

Location

Bundesinstitut für Erwachsenenbildung (bifeb)

Bürglstein 1-7

5360 Strobl, Austria

Registration / Waiting List

Please submit your **request for registration by 1 February 2026** via email to:

Katharina Schlack, Katharina.Schlack@plus.ac.at

Registration Fees

Membership in one of the sponsoring societies is mandatory. Please note that some of the societies offer free student membership.

Academic / Government:	490 Euro
Business / Industry:	650 Euro
Student:	360 Euro

Accommodation

Accommodation and food are ***included*** in the registration fees. Depending on room availability, student participants may need to be accommodated in *double rooms*.

How to Get There

Please see the description (in German) at
http://www.bifeb.at/das-bifeb/kontakt

Contact & Information

For questions, please ask

Katharina Schlack or Arne Bathke
Universität Salzburg,
Dep. of Artificial Intelligence and Human Interfaces
Jakob-Haringer-Str. 6
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Tel. +43 (0)662 8044 5343
Katharina.Schlack@plus.ac.at

Cancellation

Your registration will become binding on **15 April 2026**.

If you have to cancel, we will try to admit someone from the waiting list. However, if this it not possible and your cancellation is on 16 April 2026 or later, your registration fees cannot be returned.

Österreichische Statistische Gesellschaft

Deutsche und Österreich-Schweizer Region der Internationalen Biometrischen Gesellschaft (IBS-DR, -ROeS)
Österreichische Statistische Gesellschaft (ÖSG)
R Trustworthy Data Science and Security, TU Dortmund
Intelligent Data Analytics Lab, Universität Salzburg

PARIS LODRON UNIVERSITÄT SALZBURG
Lab for Intelligent Data Analytics Salzburg

UA RUHR | CENTER FOR TRUSTWORTHY DATA SCIENCE AND SECURITY RESEARCH ALLIANCE

Summer School 2026

Surrogate Endpoint Evaluation in Clinical Trials

23 – 26 June, 2026
Strobl am Wolfgangsee, Austria

Instructors

Geert Molenberghs (Hasselt & Leuven)
Ariel Alonso (Leuven)
Wim Van der Elst (J&J)

The concept of surrogacy

Surrogate endpoints have gained increasing importance in clinical trials as they provide a shortcut to evaluate the efficacy of a treatment in a faster, more efficient, and cost-effective way. However, surrogate endpoints have also generated controversy due to their limitations, such as the lack of direct clinical relevance or the risk of false-positive results. Given the growing interest and debate surrounding surrogate endpoints, it is important to provide a comprehensive course that covers the fundamental concepts, applications, and challenges of surrogate endpoints in clinical research.
The course will provide participants with a deep understanding of the principles behind the evaluation and application of surrogate endpoints in clinical trials. In addition, it will cover several modern approaches for their evaluation within the two main schools of thought in this area, namely, the causal inference and meta-analytic schools. The course will also address implementation of these advanced methods in R and SAS.

Learning outcomes

1. Participants will have a clear understanding of the potential and limitations related to the use of surrogate endpoints in clinical research
2. Participants will get familiar with the most modern methodologies proposed for the evaluation of surrogate endpoints
3. Participants will get familiar with the use of surrogate endpoints in several relevant clinical domains

Participants will get familiar with SAS packages and R libraries that implement the state-of-the-art methods for the evaluation of surrogate endpoints

Course Outline

The course will start by introducing the definition and purpose of surrogate endpoints, the regulatory context, and a historical perspective about their use and methodological evaluation. Firstly, we will start with the basic definitions and the first approaches proposed by Prentice (1989), Freedman (1992) and Molenberghs and Buyse (1998). Secondly, after discussing the limitations of these pioneering ideas, the course will continue with the introduction of more advanced and modern techniques introduced within the meta-analytic framework along the lines of Molenberghs and Buyse (2000). In this framework, it is assumed that information on the surrogate and true endpoint from several clinical trials is available. The definitions of surrogacy at the trial and individual level will be presented and different modeling frameworks will be discussed to assess these quantities. Several case studies will be analyzed, and the implementation of the meta-analytic approach will be illustrated using R (Surrogate package) and SAS.

We will then focus on the use of information-theory and causal inference for the evaluation of surrogate endpoints in the single trial setting. In this setting, it is assumed that information on the surrogate and true endpoint from a single clinical trial is available. A general definition of surrogacy based on the concept of information gain or, equivalently, uncertainty reduction will be introduced. To assess the definition, a general metric of surrogacy, the so-called individual causal association (ICA), will be presented and its properties will be discussed. The ICA is based on causal inference models, and several of these models will be presented. The unidentifiability issues that typically appear when working with causal inference models will be handled via sensitivity analysis. Several case studies will be presented, and the implementation of the methodology in R via the Surrogate package will be discussed.

Presenters

Geert Molenberghs (geert.molenberghs@uhasselt.be) is Professor of Biostatistics at the Universiteit Hasselt and KU Leuven in Belgium. BS degree in mathematics (1988) and PhD in biostatistics (1993) from the Universiteit Antwerpen. Methodological work on surrogate markers in clinical trials, categorical data, longitudinal data analysis, and on the analysis of non-response in clinical and epidemiological studies. Joint Editor for Applied Statistics, Co-editor for Biometrics, Co-editor for Biostatistics, Series Editor of Wiley Probability & Statistics, and Wiley StatsRef. Currently Executive Editor of Biometrics. Associate Editor for several journals. Past President of the International Biometric Society, elected Fellow of the American Statistical Association, Guy Medal in Bronze from the Royal Statistical Society. Visiting positions at Harvard School of Public Health (Boston, MA). Founding director of the Center for Statistics at Hasselt University; director of the Interuniversity Institute for Biostatistics and statistical Bioinformatics, I-BioStat. Has (co-)taught nearly 200 short and longer courses on the topic in universities as well as industry, in Europe, North America, Latin America, and Australia. Advisor to the government and member of several official scientific boards in Belgium. ±850 publications, of which: ±650 international peer-reviewed: ±80 proceedings; 15 invited discussions; 4 book reviews; 9 book editorships; 9 monographs as author; ±65 chapters; ±25 local and outreach contributions.

Ariel Alonso Abad (ariel.alonsoabad@kuleuven.be) is Associate Professor at KU Leuven in Belgium. BS (1992) and MS (1997) degree in mathematics from the University of Havana, Cuba. MS and PhD in Biostatistics from Hasselt University in Belgium, 1998 and 2004. Consultant, National Coordination Center for Clinical Trials in Havana, Cuba; Assistant Professor, University of Maastricht; post-doctoral researcher and part-time professor, Hasselt University. Research on the evaluation of surrogate endpoints and development of information-theoretic approaches within the meta-analytic and causal inference paradigms. Co-author of R package Surrogate, implementing advanced methods for the evaluation of surrogate endpoints. Approximately 100 scientific papers; textbook "Applied Surrogate Endpoint Evaluation with SAS and R." Has supervised 11 PhD students and 24 master students and taught 13 short courses globally.

Wim Van der Elst (wvandere@its.jnj.com) is Non-Clinical Statistician at Johnson & Johnson. MS degree in psychology (2001) and biostatistics (2012), PhD in psychology (2006) and in statistics (2016). At J&J, supporting the neuroscience therapeutic area (with a focus on neurodegenerative diseases such as Alzheimer's and Parkinson's disease). Research on evaluation of surrogate endpoints, development of normative data, and psychometric evaluation of cognitive scales. Published about 100 scientific papers, co-author of textbook and R package (see above) on surrogate endpoint evaluation.