

Leading international collaborations to build consensus: Developing the SAPI Guideline within the STRATOS Initiative

Marianne Huebner, Michigan State University

The STRATOS (STRengthening Analytical Thinking for Observational Studies) Initiative is an international volunteer network of expert biostatisticians dedicated to improving the design, analysis, and reporting of observational research through practical statistical guidance and education. Its central mission is to bridge the gap between methodological developments and routine research practice by translating complex statistical concepts into accessible recommendations for analysts with diverse backgrounds.

This presentation uses the development of the Statistical Analysis Plan for Observational Studies with Initial Data Analysis (SAPI) guideline as a case study of an international Delphi consensus process. The project brought together statisticians and methodological experts from multiple countries to address the lack of guidance for statistical analysis plans in observational research and to promote transparent documentation and pre-planning of initial data analysis, data quality assessment, and analytical decision-making. Topics include defining project scope, selecting expert participants, conducting Delphi surveys, balancing methodological rigor with practical applicability, managing disagreements, and sustaining engagement in a volunteer-led international collaboration. The SAPI experience illustrates the value of international scientific networks such as STRATOS in translating methodological innovation into better research.

Developing recommendations to handle patient reported outcome data in oncology cancer trials

Saskia le Cessie, Leiden University Medical Center

In this talk I will discuss the involvement of STRATOS in the SISAQOL-IMI project. The SISAQOL-IMI Consortium aims to develop standards for designing, analysing, presenting and interpreting health-related quality of life (HRQOL) and patient-reported outcome (PRO) data in cancer clinical trials. It is an international, multidisciplinary consortium, involving regulatory agencies, health technology assessment bodies, the pharmaceutical industry, and academic and professional societies alongside experts in statistics, PRO measurement, clinical oncology, and patient advocacy. Recently, the SISAQOL-IMI consortium delivered its final recommendations (see <https://www.sisaqol.org/>). In this talk we describe these results with an emphasis of the contribution of STRATOS members and discuss some of the challenges collaborating in such an interdisciplinary consortium.

Focusing on relevant Estimands. Quality of life among the living combined with the survival comparison: a legitimate target of evidence for treatment choice.

Els Goetghebeur, Ghent University

The field of causal inference is devoted to bringing evidence on which interventions may best improve outcomes for the treated.

In an ideal world this starts from exchangeable groups, representative of a well-defined target population, which are assigned different treatments at onset. Outcomes of interest are then assessed over regular follow-up times until the study ends or patients die. How these outcomes compare at different follow-up times sheds light on what to expect under different treatment choices in target populations.

In frail populations such as late-stage oncology or in residential care centres a substantial number of patients may die during follow-up. How to interpret quality of life (QoL) after one year in the target population is then less obvious. Surprisingly, popular methods have sought to (implicitly) impute QoL after death before comparing 'augmented' results for the 'full' population that started treatment. Alternatively, composite outcomes, such as percentage with 'deteriorated QoL or death' have been reported for treatment comparisons. While the first reports appear to 'cancel' death in an attempt to avoid 'selection bias by death', the second reports no longer treat death as quite distinct from a special QoL value in the summarized endpoint. In this talk we argue that a third approach that focuses on the real-world experienced outcome in survivors, is highly relevant. It can recognize the distinct role of death and QoL-while-alive in a 2-dimensional

Teaching Initial Data Analysis: Bringing Research Advances into the Classroom

Lara Lusa, University of Primorska

The talk presents our efforts to integrate in teaching the current developments in the research conducted by the topic group on Initial Data Analysis (IDA) within the STRATOS initiative. IDA comprises all the steps between the end of data collection and the beginning of the analysis addressing the research questions. Despite its substantial impact on transparency, reproducibility, and validity, IDA is often conducted without a formal plan or is insufficiently documented. IDA is usually not thought in undergraduate and graduate courses of statistics, it is expected that this aspect of data analysis is not sufficiently understood by applied researchers. We present a case study based on the dataset that describes the characteristics of the Pokémon species, where we developed teaching activities to introduce students to effectively using IDA.

