Clinical Biostatistics and Data Science Seminar
August 12 (Wed) 2026 at the ISM, Tokyo

Copula models in surrogate endpoint validation

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Organizers: Research Center for Medical and Health Data Science, the ISM;
Department of Clinical Biostatistics, Kyoto University SPH

Venue: The Institute of Statistical Mathematics:
10-3 Midori-cho, Tachikawa, Tokyo 190-8562, Japan

- 15:00- Opening Remark by Professor **Takeshi Emura**
- 15:10-16:10 Talk by Professor **Tomasz Burzykowski**
- Q & A
- 16:20-16:50 Panel discussion
- 17:00 Closing

Discussants:


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Professor Koji Oba: Interfaculty Initiative in Information Studies, the University of Tokyo, Japan
Dr. Munechika Misumi: Department of Statistics, Radiation Effects Research Foundation, Japan
Dr. Ming-Chung Chang: The Institute of Statistical Science, Academia Sinica, Taiwan
Professor Takeshi Emura: School of Informatics and Data Science, Hiroshima University, Japan

Abstract

In a clinical trial, a surrogate endpoint (for instance, a biomarker) is intended to replace a clinical endpoint (for instance, overall survival) for the evaluation of new treatments when it can be measured more cheaply, more conveniently, more frequently, or earlier than that clinical endpoint. A surrogate endpoint is expected to predict clinical benefit, harm, or lack of these.

For two normally distributed endpoints, Buyse *et al.* (2000) suggested to evaluate the strength of evidence for surrogacy by using data from multiple randomized clinical trials. In this so-called meta-analytic framework, the suitability of a candidate surrogate endpoint is evaluated by a quantitative assessment of the prognostic value of the candidate for the clinical outcome ("individual-level surrogacy") and of the predictive value of treatment effects on the candidate for the effects on the clinical outcome ("trial-level surrogacy").

Burzykowski *et al.* (2001) extended the meta-analytic approach to the case of two failure-time endpoints by using bivariate survival modelling based on copula models. Subsequently, Burzykowski *et al.* (2004) proposed a copula-based model to address the problem of evaluating an ordinal categorical or binary endpoint as a surrogate for a failure-time clinical outcome.

In this talk, a summary of the copula-based approaches to the evaluation of surrogate endpoints will be offered and illustrated by using actual data from cancer clinical trials. Additionally, extensions of the original ideas that allow for, e.g., inclusion of random effects will be discussed.

References:

- Burzykowski T, Molenberghs G, Buyse M, Geys H, Renard D (2001) Validation of surrogate end points in multiple randomized clinical trials with failure time end points. *JRSS C*, 50, 405-422.

- Burzykowski T, Molenberghs G, Buyse M (2004) The validation of surrogate endpoints using data from randomized clinical trials: a case-study in advanced colorectal cancer. *JRSS A,* 167, 103–124.

- Buyse M, Molenberghs G, Burzykowski T, Renard D, Geys H (2000) The validation of surrogate endpoints in meta-analysis of randomized experiments. *Biostatistics*, 1, 49–68.

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