

Simulation panel

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Data-driven simulations

JOURNAL ARTICLE ACCEPTED MANUSCRIPT

Data-Driven Simulations to Assess the Impact of Study Imperfections in Time-to-Event Analyses

Michal Abrahamowicz , Marie-Eve Beauchamp, Anne-Laure Boulesteix, Tim P Morris, Willi Sauerbrei, Jay S Kaufman, on behalf of the STRATOS Simulation Panel [Author Notes](#)

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Simulation Panel: “Data-Driven Simulations” (project completed in 2024)

Using novel “Data-Driven Simulations” approach as a *Quantitative Bias Assessment (QBA)* tool to systematically **evaluate the expected Impact of relevant data/study imperfection(s)** on the results and conclusions of – possibly complex – statistical analyses of a **specific real-world study**.

[1] (*Am J Epi (AJE)* 2024)

Main Goals:

- To **develop a systematic 7-step approach to simulate** multivariable data, that resemble closely the specific real-world dataset of interest, including the relevant imperfections, but offer control over the ‘true’ associations of primary interest, with **main focus on Time-to-Event Analyses**, possibly with time-varying exposures/covariates.
- To **illustrate (i) implementation of, and (ii) insights offered by this approach in 2 different real-world time-to-event analyses.**

[1] = Abrahamowicz M, Beauchamp ME, Boulesteix AL, Morris TP, Sauerbrei W, Kaufman JS, on behalf of the STRATOS Simulation Panel. Data-Driven Simulations to Assess the Impact of Study Imperfections in Time-to-Event Analyses. *Am J Epidemiol* 2024. <https://doi.org/10.1093/aje/kwae058>. *Online publication ahead of print.*]

‘Phases’ proposal



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RESEARCH ARTICLE

Biometrical Journal →

Phases of methodological research in biostatistics—Building the evidence base for new methods

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Ian R. White⁴ | on behalf of the Simulation Panel of the STRATOS initiative**

Extending/concreting 'phases' ideas

We like the idea of phases, not least because it:

1. Helps frustrated statisticians understand why no-one is using their ideas
2. Gives applied researchers a way to articulate hesitation

We would be keen to hear from people who are sceptical.

In particular, it's hard to say what constitutes a particular phase, particularly 'late-phase' that help get methods fit-for-purpose. We're working on it!

Handling ‘method failure’

On the handling of method failure in comparison studies

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Handling method failure

Sometimes one or more methods fail to return a meaningful result in one or more datasets.

Discusses how to think about method failure and options for handling it (spoiler: method failure does not produce ‘missing data’).

(a) Hypothetical simulation study

Bias	Unconditional (all repetitions)	Conditional (repetitions where A does not fail)
Method A	-	0.09
Method B	0.14	0.09