

Context

- Observational studies pose many design and statistical challenges
- Valid observational research depends on careful study design, high data quality, appropriate statistical methods and accurate interpretation of results

The Problem

- Statistical methods has seen exponential advancements
 - diffusion of methodological innovation is slow
 - many developments are not applied in practice
- Even worse, 'standard' analyses reported in the medical literature are often based on unrealistic assumptions or use inappropriate methods, casting doubt on their results and conclusions
- Analysts, reviewers, editors, readers and many more stakeholders and consumers need guidance for key issues in the design and analysis of observational studies

Filling the Gap: The STRATOS initiative

- The STRengthening Analytical Thinking for Observational Studies (STRATOS) initiative was launched in August 2013
- In May 2025
 - >100 researchers from 20 countries worldwide with background in biostatistical and epidemiological methods
 - Connected with leading international organisations, e.g.,
 - International Society of Clinical Biostatistics (ISCB), and
 - International Biometric Society (IBS)

- Interested in CONTRIBUTING?

<http://www.stratos-initiative.org/en/contact>



STRATOS Objectives

- Provide accessible and evidence-based guidance for key topics in the design and analysis of observational studies
- Guidance is intended for applied statisticians and other data analysts with varying levels of statistical education, experience and interests

Organisational Structure

STRATOS is led by an **Executive Committee** and a **Steering Group**. It has the following topic groups and cross-cutting panels:

Topic Groups (TGs)		Panels	
1	Missing data	MP	Membership
2	Selection of variables and functional forms in multivariable analysis	PP	Publications
3	Initial data analysis	GP	Glossary
4	Measurement error and misclassification	WP	Website
5	Study design	SP	Simulation Studies
6	Evaluating diagnostic tests and prediction models	TED	Towards Excellent Data
7	Causal Inference	TP	Knowledge Translation
8	Survival analysis	CP	Contact Organizations
9	High-dimensional data	VP	Visualisation
		OS	Open Science

Membership:

Regular: Experienced researchers who contribute regularly to STRATOS TG +/- panel activities

Experienced Adjunct: Experienced researchers who contribute occasionally to STRATOS activities

Early Career Adjunct: Researchers at early career stages who participate in TG +/- panel activities

Clinical Affiliate: Clinicians involved in research with relevant statistical expertise

Framework for Guidance Development

Guidance is aimed at users with three levels of statistical knowledge:

Level 1: Low statistical knowledge

- Propose acceptable methods that are easily implemented
- Highlight weaknesses of common approaches

Level 2: Experienced statistician

- Refer to advantages and disadvantages of competing approaches
- Propose advanced methodology feasible by experienced analysts

Level 3: Expert in a specific area

- Consider recent developments with statements about possible advantages and disadvantages
- Identify areas needing more methodological research or guidance

Stages in Guidance Development

Phase I: Experts need to work on state-of-the-art methods and develop guidance for knowledge level 2. Comparisons (simulations) required!

Phase II: Extend guidance to level 1 (simpler methods but still acceptable) and experts work on improved methodology aiming to improve level 2 guidance

Activities & Publications

Important Meetings/Mini-Symposia

- ISCB conferences since 2013
- IBS - Invited sessions at IBC (2016, 2020, 2022, 2024) and at many regional meetings
- Banff International Research Station, Canada (general meetings in 2016, 2019)
- 3rd STRATOS workshop in Leiden, Netherlands (2024)

Introductory Publication

- Sauerbrei W, Abrahamowicz M, Altman DG, le Cessie S, Carpenter J on behalf of the STRATOS initiative. STRengthening Analytical Thinking for Observational Studies: the STRATOS initiative. *Stat Med* 2014; 33:5413-5432

Publications and Talks

- Publications by all Topic Groups and the Simulation Panel
- **Series of short papers** from the Topic Groups, several panels and projects in the **Biometric Bulletin** of IBS (4 per year, since 03/2017). They provide an overview of activities.
- All papers and slides from nearly all talks since 2013 are available on the website. <http://www.stratos-initiative.org/> (...publications, news, archive).
- <https://www.youtube.com/@TheSTRATOSInitiative> started recently