

STRengthening Analytical Thinking for Observational Studies

Session 1 - Methodological Aspects

Willi Sauerbrei¹ and Georg Heinze² for the STRATOS initiative

¹Institute for Medical Biometry and Statistics, Medical Center - University of Freiburg, Freiburg, Germany

²Institute of Clinical Biometrics, Center for Medical Data Science, Medical University of Vienna, Vienna, Austria

Overview

Motivation for STRATOS

Structure

Cooperations

Launch of the STRATOS initiative 2013

Mini-Symposium on the last day of the ISCB2013 meeting in Munich

Why do we need such an initiative?

- Weaknesses of many analyses
- Many analyses are conducted by people with **limited statistical knowledge**
- Analysis of observational studies – issues are very **similar in all areas of science**
- Rapid developments of statistical methodology requires **guidance and education**

Guidance and education required

- Statistical models are always a simplification of real life processes. To improve these models, researchers develop new and more complicated approaches
- Different and partly conflicting approaches are proposed
- Expert knowledge is required to use methods
- Statistical software has to be available

Current situation

- Statistical methodology has seen substantial development
- Computing facilities can be viewed as the cornerstone
- Resampling, Bayesian and simulation-based methods allow investigations that were impossible five decades ago
- Machine learning approaches are now competitors of the more traditional statistical approaches
- Wealth of new statistical software packages and AI-assisted coding allow a rapid implementation and verification of new statistical ideas
- When consulted, LLMs often suggest ‘mainstream’ methods, but not always the optimal ones

Unfortunately, many sensible improvements are ignored in practical statistical analyses

STRATOS Topic Groups (TGs)

Topic Group		Chairs
1	Missing data	James Carpenter (UK), Kate Lee (AUS)
2	Selection of variables and functional forms in multivariable analysis	Georg Heinze (AUT), Aris Perperoglou (UK), Willi Sauerbrei (GER)
3	Initial data analysis	Marianne Huebner (US), Lara Lusa (SL), Carsten Oliver Schmidt (GER)
4	Measurement error and misclassification	Paul Gustafson (CAN), Pam Shaw (US)
5	Study design	Suzanne Cadarette (CAN), Rima Izem (CH)
6	Evaluating diagnostic tests and prediction models	Ewout Steyerberg (NL), Ben van Calster (BEL)
7	Causal inference	Els Goetghebeur (BEL), Bianca de Stavola (UK)
8	Survival analysis	Michal Abrahamowicz (CAN), Malka Gorfine (IS), Terry Therneau (US)
9	High-dimensional data	Federico Ambrogi (IT), Riccardo de Bin (NOR), Lisa McShane (US)

Chairs from 13 countries and 4 continents

STRATOS Cross-cutting Panels

Panel		Chairs
MP	Membership	James Carpenter (UK), Willi Sauerbrei (GER)
PP	Publications	Mark Baillie (CH), Anne-Laure Boulesteix (GER), Pam Shaw (US)
GP	Glossary	Martin Boeker (GER), Marianne Huebner (US)
WP	Website	Joerg Rahnenfuehrer (GER), Willi Sauerbrei (GER)
SP	Simulation Studies	Michal Abrahamowicz (CAN), Anne-Laure Boulesteix (GER)
TED	Towards Excellent Data	Georg Heinze (AUT), Carsten Oliver Schmidt (GER)
TP	Knowledge Translation	Maarten van Smeden (NL)
CP	Contact Organisations	Willi Sauerbrei (GER)
VP	Visualisation	Mark Baillie (CH)
OS	Open Science	Daniela Dunkler (AUT), Sabine Hoffmann (GER)

Cooperations

STRATOS was influenced by reporting guidelines, for more than a decade coordinated by the Enhancing the QUALity and Transparency Of health Research (**EQUATOR**) network and is an intellectual child of **ISCB** (Sauerbrei, Abrahamowicz, le Cessie, 2016).

The STRATOS Initiative - Motivation, Mission, Structure and Main Aims

From Willi Sauerbrei, Michal Abrahamowicz and Saskia Le Cessie, for the STRATOS initiative ISCB News #62

- International Biometric Society (**IBS**)

Overview of activities from TGs, panels and projects in 36 articles of the Biometric Bulletin

At IBC 2026: Hotly debated topics in Biostatistics: A STRATOS perspective

- 2019 Partner in the **SISAQOL** (Setting International Standards in Analysing Patient-Reported Outcomes and Quality of Life Endpoints; <https://www.sisaqol-imi.org/>) project. Lead by EORTC (<https://eortc.org/>). 41 stakeholders, including pharma and regulators

Biometric Bulletin – STRATOS initiative has a series with short articles since 3/2017

First in a Series of Papers for the Biometric Bulletin

**STRATOS initiative – Guidance for designing and
analyzing observational studies**

Willi Sauerbrei¹, Marianne Huebner², Gary S. Collins³, Katherine Lee⁴, Laurence Freedman⁵, Mitchell Gail⁶, Els Goetghebeur⁷, Joerg Rahnenfuehrer⁸ and Michal Abrahamowicz⁹ on behalf of the STRATOS initiative.

Biometric Bulletin 2017(3)

Each author represents one TG

a very brief update on the achievements of the STRATOS initiative in the last 5 years

Willi Sauerbrei¹, Michal Abrahamowicz², Mark Baillie³, Bianca De Stavola⁴, Mitchell Gail⁵, Marianne Huebner⁶, Ruth Keogh⁷ and Pamela A. Shaw⁸ for the STRATOS initiative

Biometric Bulletin 2022(3)

Authors: members of ExCom and chairs of
the Publication Panel

Sept 2017:	introduction of the initiative
Dec 2017 – March 2020:	9 TG articles
June 2020 – Dec 2020:	Panels Simulation, Visualisation and Glossary
Since March 2021:	updated articles for several TGs, 5y update of STRATOS, Data quality, Open Science, Summary of level 1 material,

Summary: Guidance is needed, research is required!!

- Data and data science becomes more and more important
- Answering questions empirically through data analyses often requires the use of complex methodology. It is important to develop suitable approaches; needs to be done by experts (Level 3)
- Experienced statisticians (Level 2) need to be supported by suitable guidance. There are (too) many approaches (some are useless, but which?) available and suitable comparisons are missing
- Better simulation studies are required to assess properties, compare approaches and derive evidence based guidance for practice
- Suitable educational material is the key to improve analyses at a broad level
- For practically relevant topics we need greater emphasis on development of Level 1 and 2 guidance

The logo for the Stratos Initiative. It features the word "STRATOS" in a large, dark blue, sans-serif font. A green bar chart with five bars of increasing height is integrated into the letter "A". Below "STRATOS" is the word "INITIATIVE" in a smaller, green, sans-serif font.

Level 1

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Finding STRATOS

<https://stratos-initiative.org/>



A big thanks to all members,
specifically to the colleagues leading a
topic group or a panel!