

Statistical guidance – mainly from reporting guidelines!

Supplementary Material J. External sources of statistical guidance.

Supplementary Table J1. Number of journals referring to specific reporting guidelines.

Reporting guideline	Journals (<i>n</i>)
Consolidated Standards of Reporting Trials (CONSORT)	95
Animal Research: Reporting of In Vivo Experiments (ARRIVE)	80
Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)	47
REporting recommendations for tumour MARKer prognostic studies (REMARK)	40
The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)	39
Standards for Reporting Diagnostic accuracy studies (STARD)	36
International Committee of Medical Journal Editors (ICMJE) Recommendations	21
Consolidated Health Economic Evaluation Reporting Standards (CHEERS)	18
STrengthening the REporting of Genetic Association Studies (STREGA)	16
National Institutes of Health (NIH) Recommendations	14
Meta-analysis Of Observational Studies in Epidemiology (MOOSE)	12
CAse Report (CARE)	11
Minimum Information About a Microarray Experiment (MIAME)	11
Consolidated criteria for reporting qualitative research (COREQ)	9
Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)	9
Transparent reporting of a multivariable prediction model for individual prognosis or diagnosis (TRIPOD)	9

Supplementary Table J2. Number of journals referring to guidance in other external sources (not reporting guidelines). DOIs or URLs are in brackets when available.

External statistical guidance	Journals (<i>n</i>)
Cummings & Rivara 2003 (10.1001/archpedi.157.4.321)	3
Cumming et al. 2007 (10.1083/jcb.200611141)	2
Olsen 2003 (10.1128/iai.71.12.6689-6692.2003)	2
Olsen 2014 (10.1128/iai.00811-13)	2
Richardson & Overbaugh 2005 (10.1128/jvi.79.2.669-676.2005)	2
Altman et al. 1983 (10.1136/bmj.286.6376.1489)	1

...

Examples of guidance – sufficient details?

Bayesian statistics

“For Bayesian analysis, [report] information on the choice of priors and Markov chain Monte Carlo settings.”

(Scientific Data)

Categorisation of continuous data

“Categorizing of continuous data (e.g. into quartiles, quintiles) is discouraged. It leads to a loss of information, usually needs more complicated methods than for continuous data and introduces demarcations which are valid only for this particular study.”

(European Heart Journal)

Handling outliers

“How were outliers defined and handled? Were they defined before the beginning of the study? Have you reported outliers that were excluded?...Data pre-processing steps such as transformations, re-coding, re-scaling, normalization, truncation, and handling of below detectable level readings and outliers should be fully described; any removal or modification of data values must be fully acknowledged and justified.”

(Science Translational Medicine)

Handling missing data

“Report losses to observation, such as dropouts from a clinical trial or those lost to follow-up or unavailable in an observational study. Consider multiple imputation methods to impute missing data and include an assessment of whether data were missing at random. Approaches based on “last observation carried forward” should not be used.”

(JAMA Internal Medicine)

Guidance and educational material is needed for many stakeholders (analysts with different levels of knowledge, reviewers, readers, teachers, **journalists,**)

↓
Researchers

First in a Series of Papers for the Biometric Bulletin

STRATOS initiative – Guidance for designing and analyzing observational studies

STRATOS
INITIATIVE

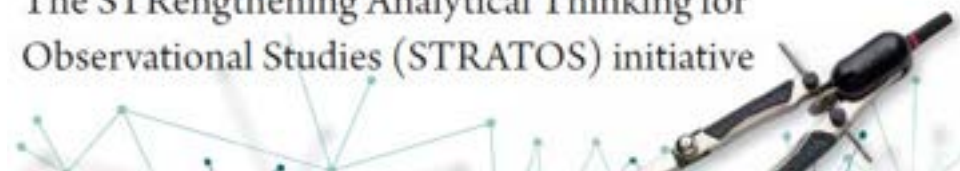
Willi Sauerbrei¹, Marianne Huebner², Gary S. Collins³, Katherine Lee⁴, Laurence Freedman⁵, Mitchell Gail⁶, Els Goetghebeur⁷, Joerg Rahnenfuehrer⁸ and Michal Abrahamowicz⁹ on behalf of the STRATOS initiative.

➔ Short papers from all TGs and some panels

↓
Consumers

Guidance for designing and analysing observational studies:

The STRengthening Analytical Thinking for Observational Studies (STRATOS) initiative



Willi Sauerbrei¹, Gary S. Collins²,
Marianne Huebner³, Stephen D. Walter⁴,
Suzanne M. Cadarette⁵, and
Michal Abrahamowicz⁶ on behalf of the
STRATOS initiative

Volume 26 Number 3 | Medical Writing September 2017 | 17

Journal of the European Medical Writers Association
(EMWA)

STRATOS – History and Milestones

2011 Epi Subcom at 42th Int Soc Clin Biostatistics (ISCB) in Ottawa

2013: Initiative launched at 44th ISCB in Munich

2014: 1st STRATOS paper [1]: *Statistics in Medicine* 2014; 33(30):5413-5432.

Sauerbrei W, Abrahamowicz M, Altman D, le Saskia, Carpenter J. *STRengthening Analytical Thinking for Observational Studies: The STRATOS initiative.*

2016 & 2019: 2 General meetings, Banff Int Res Station (BIRS), Canada



... STRATOS – History and Milestones

Invited STRATOS Sessions and Mini-Symposia:

Int Soc Clin Biost (ISCB): 2014, 2015, 2016, 2018, 2019, 2020, 2021, 2022

Int Biometric Conf (IBC): 2016, 2020, 2022 + Regional IBS meetings: 2017, 2018, 2021, 2022

Royal Statistical Soc (RSS): 2018, 2020, 2021

Other international conferences: HEC 2016, CEN 2018, GMDS 2017, Soc Epi Res (SER) 2021, DAGStat 2022

since 3/2017: Series in Biometric Bulletin with 23 short overviews published, to proceed until 4/2024

2021 Memorandum of Understanding with ISCB

2019 Partner in the Setting International Standards in Analysing Patient-Reported Outcomes and Quality of Life Endpoints (SISAQOL) project lead by EORTC (>40 stakeholders, including pharma and regulators)

As of 2023: >100 members (from 20 countries on 5 continents)



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), Carsten Oliver Schmidt (GER)
4	Measurement error and misclassification	Victor Kipnis (US), Pam Shaw (US)
5	Study design	Mitchell Gail (US), Suzanne Cadarette (CAN)
6	Evaluating diagnostic tests and prediction models	Ewout Steyerberg (NL), Ben van Calster (NL)
7	Causal inference	Els Goetghebeur (BEL), Ingeborg Waernbaum (SWE)
8	Survival analysis	Michal Abrahamowicz (CAN), Malka Gorfine (IS), Terry Therneau (US)
9	High-dimensional data	Lisa McShane (US), Joerg Rahnenfuehrer (GER), Riccardo de Bin (NOR)

Chairs from 11 countries and 4 continents

STRATOS Cross-cutting Panels

Panel		Chairs
MP	Membership	James Carpenter (UK), Willi Sauerbrei (GER)
PP	Publications	Bianca De Stavola (UK), Mitchell Gail (US), Pam Shaw (US), Mark Baillie (CH)
GP	Glossary	Martin Boeker (GER), Marianne Huebner (US)
WP	Website	Joerg Rahnenfuehrer (GER), Willi Sauerbrei (GER)
RP	Literature Review	Gary Collins (UK), Carl Moons (NL)
BP	Bibliography	to be determined
SP	Simulation Studies	Michal Abrahamowicz (CAN), Anne-Laure Boulesteix (GER)
DP	Data Sets	Saskia Le Cessie (NL), Maarten van Smeden (NL)
TP	Knowledge Translation	Maarten van Smeden (NL)
CP	Contact Organisations	Willi Sauerbrei (GER)
VP	Visualisation	Mark Baillie (CH)
OS	Open Science	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**)

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 Rahnenfuhrer⁸ and Michal Abrahamowicz⁹ on behalf of the STRATOS initiative.

Biometric Bulletin 2017(3)

Each author represents one TG

Sept 2017:

Dec 2017 – March 2020:

June 2020 – Dec 2020:

Since March 2021:

introduction of the initiative

9 TG articles

Panels Simulation, Visualisation and Glossary
updated articles for several TGs, 5y update of
STRATOS, Data quality, Summary of level 1
material, Open Science

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

Agreement with the Editor: article series until Dec. 2024

Program

- Talks of TGs 1, 2, 4, 9, the new OS panel and some projects
- For other TGs and the simulation panel - short summaries

9:50-10.15 Level 1 guidance on conducting and reporting sensitivity analyses for missing data - Lee K et al. for **TG1**

10.15-10.40 Aims of the new Open Science panel Luijken K et al. for the **Open Science panel**

- Session 2 (11.00-12.40)

11.00-11.25 Ongoing research towards state-of-the-art in variable and functional form selection for statistical models - Heinze G et al. for **TG2**

11.25-11.50 How to include time-varying exposures prone to measurement error in survival analyses - Proust-Lima C et al. for **TG4**

11.50-12.15 Evaluating the impact of covariate measurement error on functional form estimation in regression modelling - Perperoglou A et al. for **TG2 and TG4**

12.15-12.40 Statistical analysis of high-dimensional biomedical data: A gentle introduction to analytical goals, common approaches and challenges - Ambrogi F et al. for **TG9**

Program

- Session 3 (13.30-15.10)
 - 13.30-13.55 The slowly changing landscape of predictive modeling in biomedicine - Lusa L et al.
 - 13.55-14.20 Counterfactual prediction for personalized healthcare using observational data - Van Geloven N et al. for **TG6 and TG7**
 - 14.20-14.45 Recommendations to handle patient reported outcome data in oncology cancer trials - Le Cessie S et al. on behalf of work package 3 of the **SISAQOL-IMI consortium**
 - 14.45-15.10 Comparing quality of life - while alive - between treatment and (external) controls: methods for real world analysis in clinical trials - Goetghebeur E et al. on behalf of work package 3 of the **SISAQOL-IMI consortium**
- Session 4 (15.30-16.30)
 - Panel discussion** about the future of STRATOS Chair: Carpenter J (London, UK)

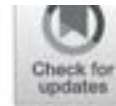
TG3 – Initial data analysis

OA A Contemporary **Conceptual Framework for** Initial Data Analysis

Marianne Huebner, Saskia le Cessie, Carsten O. Schmidt, Werner Vach

Observational Studies 2018

Hidden analyses: **a review** of reporting practice and recommendations for more transparent reporting of initial data analyses



Marianne Huebner^{1,2*}, Werner Vach³, Saskia le Cessie⁴, Carsten Oliver Schmidt⁵, Lara Lusa^{6,7} and on behalf of the Topic Group "Initial Data Analysis" of the STRATOS Initiative (STRengthening Analytical Thinking for Observational Studies, <http://www.stratos-initiative.org>)

BMC Medical Research Methodology 2020

Ten simple rules for initial data analysis

Mark Baillie¹, Saskia le Cessie², Carsten Oliver Schmidt³, Lara Lusa⁴, Marianne Huebner^{5*}, for the Topic Group "Initial Data Analysis" of the STRATOS Initiative¹

PLoS ONE Comput Biol 2022

Biometric Bulletin

Introducing the Initial Data Analysis Topic Group (TG3)

Schmidt CO, Vach W, le Cessie S, Huebner M on behalf of STRATOS TG3, 2/2018

Introducing the Initial Data Analysis Topic Group (TG3)

le Cessie S, Schmidt CO, Lusa L, Baillie M, Huebner M on behalf of TG3 3/2021

TG5 – Study design

Design choices for observational studies of the effect of exposure on disease incidence

Mitchell H Gail ,¹ Douglas G Altman,² Suzanne M Cadarette,³ Gary Collins,⁴
Stephen JW Evans,⁵ Peggy Sekula ,⁶ Elizabeth Williamson,⁷ Mark Woodward⁸

BMJ open 2019

Biometric Bulletin

Introducing the Study Design Topic Group (TG5)

Mitchell H. Gail and Suzanne Cadarette, 2/2019

TG6 – Evaluating diagnostic tests and prediction models

Flawed external validation study of the ADNEX model to diagnose ovarian cancer

B Van Calster, a,b,* EW Steyerberg, b,1 T Bourne, a,c,d D Timmerman, a,c GS Collins, e,1 and on behalf of TG6 of the STRATOS initiative

Gynecological Oncology Reports 2016

Calibration: the Achilles heel of predictive analytics

Ben Van Calster^{1,2,*}, David J. McLernon^{3,6}, Maarten van Smeden^{2,4,6}, Laure Wynants^{1,5}, Ewout W. Steyerberg^{2,6}
On behalf of Topic Group 'Evaluating diagnostic tests and prediction models' of the STRATOS initiative⁶

BMC Medicine 2019

Biometric Bulletin

Introducing the Topic Group on Evaluating Diagnostic Tests and Prediction Models (TG6)

Ben Van Calster, Ewout Steyerberg, 1/2020

Progress in the Topic Group on Evaluating Diagnostic Tests and Prediction Models (TG6)

Ewout W Steyerberg, Ben Van Calster, 2/2022

Three myths about risk thresholds for prediction models

Laure Wynants^{1,2*}, Maarten van Smeden^{3,4}, David J. McLernon⁵, Dirk Timmerman^{1,6}, Ewout W. Steyerberg⁴, Ben Van Calster^{1,4} and on behalf of the Topic Group 'Evaluating diagnostic tests and prediction models' of the STRATOS initiative

BMC Medicine 2019

Validation of prediction models in the presence of competing risks: a guide through modern methods

Nan van Geloven,¹ Daniele Giardiello,^{1,2} Edouard F Bonneville,¹ Lucy Teece,³ Chava L Ramspek,⁴ Maarten van Smeden,⁵ Kym I E Snell,³ Ben van Calster,^{1,6} Maja Pohar-Perme,⁷ Richard D Riley,³ Hein Putter,¹ Ewout Steyerberg,^{1,8} on behalf of the STRATOS initiative

BMJ 2022


Assessing Performance and Clinical Usefulness in Prediction Models With Survival Outcomes: Practical Guidance for Cox Proportional Hazards Models


David J. McLernon, PhD; Daniele Giardiello, MSc; Ben Van Calster, PhD; Laure Wynants, PhD; Nan van Geloven, PhD; Maarten van Smeden, PhD; Terry Therneau, PhD; and Ewout W. Steyerberg, PhD; for topic groups 6 and 8 of the STRATOS Initiative*

Annals of Internal Medicine 2023

TG7 – Causal inference

Formulating causal questions and principled statistical answers

Els Goetghebeur^{1,2}  | Saskia le Cessie³ | Bianca De Stavola⁴ |

Erica EM Moodie⁵  | Ingeborg Waernbaum⁶ | “on behalf of” the topic group Causal

Inference (TG7) of the STRATOS initiative

Statistics in Medicine 2020

Biometric Bulletin

Introducing the Causal Inference Topic Group (TG7)

Waernbaum I, De Stavola B, Moodie E, le Cessie S, Goetghebeur E on behalf of STRATOS TG7, 4/2018





Some members are very active in the

Setting International Standards in Analysing Patient-Reported Outcomes and Quality of Life Endpoints (**SISAQOL**) consortium

talks by Saskia le Cessie and Els Goetghebeur

TG8 – Survival analysis

Analysis of time-to-event for observational studies: Guidance to the use of intensity models

Per Kragh Andersen¹ | Maja Pohar Perme² | Hans C. van Houwelingen³ | Richard J. Cook⁴ | Pierre Joly⁵ | Torben Martinussen¹ | Jeremy M. G. Taylor⁶ | Michal Abrahamowicz⁷ | Terry M. Therneau⁸

Statistics in Medicine 2020

Joint project with TG6

Biometric Bulletin

Introducing the Survival Analysis Topic Group (TG8)

Andersen PK, Abrahamowicz M, Therneau TM on behalf of STRATOS TG8, 3/2019

Simulation Panel (SP) –

Simulations are the key instrument to assess and compare statistical methods

On the necessity and design of studies comparing statistical methods

Anne-Laure Boulesteix¹, Harald Binder², Michal Abrahamowicz³, Willi Sauerbrei²;
Simulation Panel of the STRATOS Initiative

Biom J 2018



Special Issue in Biom. Journal on neutral comparison studies

already 19 articles online
(4 of 6 SI editors are STRATOS members)

Introduction to statistical simulations in health research



Education

Anne-Laure Boulesteix¹, Rolf HH Groenwold^{2,3}, Michal Abrahamowicz⁴,
Harald Binder⁵, Matthias Briel^{6,7}, Roman Hornung¹, Tim P Morris⁸,
Jörg Rahnenführer⁹, Willi Sauerbrei⁵ for the STRATOS Simulation Panel

BMJ Open 2020

Biometric Bulletin

Introducing the Simulation Panel
Boulesteix AL, Morris T, Sauerbrei W,
Abrahamowicz M on behalf of the Simulation
Panel, 2/2020

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

Georg Heinze¹ | Anne-Laure Boulesteix² | Michael Kammer^{1,3} | Tim P. Morris⁴ |
Ian R. White⁴ | on behalf of the Simulation Panel of the STRATOS initiative

Biom J 2023



Biometric Bulletin - short overview from panels

Introducing the Simulation Panel

Boulesteix AL, Morris T, Sauerbrei W, Abrahamowicz M
on behalf of the Simulation Panel, 2/2020

Introducing the Visualisation Panel (SP)

Baillie M, Vandemeulebroecke M on behalf of the
Visualisation Panel, 3/2020

Glossary Panel (GP) – Defining common meaning for statistical terms

Boeker M, Tippmann P, Day S, Huebner M, Sauerbrei
W on behalf of the Glossary Panel, 4/2020

Introducing the Open Science Panel

Hoffmann S, Luijken K, Sauerbrei W, Shaw P,
Boulesteix AL, 2/2023

Biometric Bulletin - further papers

On the importance of Data Quality

Assessments and Initial Data Analysis

Schmidt C.O., Heinze G, Lusa L and Huebner M for
the STRATOS initiative 4/2022

Guidance for analysts with limited statistical knowledge

Heinze G, Boulesteix AL, Dunkler D, Gail M, Lee KJ,
van Calster B, Wallace M, Sauerbrei W, 1/2023

Summary

- 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

TG1 – Missing data

Framework for the treatment and reporting of missing data in observational studies: The Treatment And Reporting of Missing data in Observational Studies framework

Katherine J. Lee^{a,b,*}, Kate M. Tilling^c, Rosie P. Cornish^c, Roderick J.A. Little^d,
Melanie L. Bell^e, Els Goetghebeur^f, Joseph W. Hogan^g,
James R. Carpenter^h, on behalf of the STRATOS initiative

Journal of Clinical Epidemiology 2021

Biometric Bulletin

Introducing the Missing Data topic group (TG1)

Carpenter J, Lee KJ on behalf of STRATOS TG1, 4/2017

Update on the Missing Data Topic Group (TG1)

Carpenter J, Lee KJ on behalf of TG1, 4/2021

Original Article

A Comparison of Three Popular Methods for Handling Missing Data: Complete-Case Analysis, Inverse Probability Weighting, and Multiple Imputation

Roderick J. Little¹, James R. Carpenter^{2,3},
and Katherine J. Lee⁴, on behalf of the
STRATOS initiative

Sociological Methods & Research
1–31
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DOI: 10.1177/00491241221113873
journals.sagepub.com/home/smr


TG2 - Selection of variables and functional forms in multivariable analysis



Biometric Bulletin

Introducing the Topic Group on Selection of Variables and Functional Forms in Multivariable Analysis (TG2)

Perperoglou A, Heinze G, Sauerbrei W on behalf of STRATOS TG2, 3/2018

Systematic review of education and practical guidance on regression modeling for medical researchers who lack a strong statistical background: Study protocol

Paul Bach^{1,2,3}, Christine Wallisch^{1,2,4}, Nadja Klein⁵, Lorena Hafermann^{1,2}, Willi Sauerbrei⁶, Ewout W. Steyerberg⁶, Georg Heinze², Geraldine Rauch^{1,2,*}, for topic group 2 of the STRATOS initiative⁷

PLoS ONE 2020

Review of guidance papers on regression modeling in statistical series of medical journals

Christine Wallisch^{1,2*}, Paul Bach^{1,3}, Lorena Hafermann¹, Nadja Klein⁵, Willi Sauerbrei⁴, Ewout W. Steyerberg⁶, Georg Heinze², Geraldine Rauch^{1,*}, on behalf of topic group 2 of the STRATOS initiative⁷

PLoS ONE 2022

Recent activities of the Topic Group on Selection of Variables and Functional Forms in Multivariable Analysis (TG2)

Heinze G, Perperoglou A, Sauerbrei W on behalf of TG2 of STRATOS, 2/2021



TG4 – Measurement error and misclassification

Epidemiologic analyses with error-prone exposures: review of current practice and recommendations

Shaw PA, Deffner V, Keogh R, Tooze JA, Dodd KW, Küchenhoff H, Kipnis V, Freedman LS on behalf of Measurement Error and Misclassification Topic Group (TG4) of the STRATOS Initiative (2018)
Annals of epidemiology 28 (11): 821–828.

STRATOS guidance document on measurement error and misclassification of variables in observational epidemiology: Part 1—Basic theory and simple methods of adjustment

Ruth H. Keogh¹ | Pamela A. Shaw² | Paul Gustafson³ | Raymond J. Carroll^{4,5} | Veronika Deffner⁶ | Kevin W. Dodd⁷ | Helmut Küchenhoff⁸ | Janet A. Tooze⁹ | Michael P. Wallace¹⁰ | Victor Kipnis¹¹ | Laurence S. Freedman^{12,13}

Statistics in Medicine 2020

Analysis in an imperfect world

Michael Wallace

Significance 2020

STRATOS guidance document on measurement error and misclassification of variables in observational epidemiology: Part 2—More complex methods of adjustment and advanced topics

Pamela A. Shaw¹ | Paul Gustafson² | Raymond J. Carroll^{3,4} | Veronika Deffner⁵ | Kevin W. Dodd⁶ | Ruth H. Keogh⁷ | Victor Kipnis⁶ | Janet A. Tooze⁸ | Michael P. Wallace⁹ | Helmut Küchenhoff⁵ | Laurence S. Freedman^{10,11}

Statistics in Medicine 2020

TG9

Statistical analysis of high-dimensional biomedical data: a gentle introduction to analytical goals, common approaches and challenges



Jörg Rahnenführer¹, Riccardo De Bin², Axel Benner³, Federico Ambrogi^{4,5}, Lara Lusa^{6,7}, Anne-Laure Boulesteix⁸, Eugenia Migliavacca⁹, Harald Binder¹⁰, Stefan Michiels^{11,12}, Willi Sauerbrei¹⁰, Lisa McShane^{13*} and for topic group "High-dimensional data" (TG9) of the STRATOS Initiative

BMC Medicine 2023

Biometric Bulletin

Introducing the High-dimensional Data topic group (TG9)

McShane L, Rahnenführer J on behalf of STRATOS TG9 1/2019