

Statistical Analysis Plans

CCTS Biostatistics Core

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This page includes publications and tools that our consultants have found useful. For more information on this topic, including advice about how to apply it in your research, consider [scheduling a consultation with a biostatistician](#).

While we hope this resource list serves as a helpful starting point for other researchers, we provide no guarantee of its comprehensiveness or of the accuracy or reliability of the works cited. If you have concerns or suggestions to improve this page, please [contact us](#).

Technical Reports

Centers for Disease Control and Prevention (CDC) (2013). *Creating an Analysis Plan*. Centers for Disease Control and Prevention. https://www.cdc.gov/globalhealth/healthprotection/fetp/training_modules/9/creating-analysis-plan_pw_final_09242013.pdf.

European Medicines Agency (1998). *ICH Topic E 9: Statistical Principles for Clinical Trials*. CPMP/ICH/363/96. European Medicines Agency. <https://www.ema.europa.eu/en/ich-e9-statistical-principles-clinical-trials-scientific-guideline>.

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (2023). *ENCePP Guide on Methodological Standards in Pharmacoepidemiology*. 11.1. General considerations. 11.2. Timing of the statistical analysis plan. 11.3. Elements of the statistical analysis plan. Good references at end. European Medicines Agency. Chap. 11: Statistical analysis plan. https://www.encepp.eu/standards_and_guidances/methodologicalGuide11.shtml.

Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), and Center for Biologics Evaluation and Research (CBER) (1998). *Guidance for Industry: E9 Statistical Principles for Clinical Trials*. FDA-1997-D-0508. U.S. Department of Health and Human Services. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e9-statistical-principles-clinical-trials>.

Academic Articles

Bafeta, Aïda, Jason Bobe, Jon Clucas, et al. (2020). “Ten simple rules for open human health research”. In: *PLOS Computational Biology* 16.9. Ed. by Scott Markel, p. e1007846. DOI: 10.1371/journal.pcbi.1007846. <https://doi.org/10.1371/journal.pcbi.1007846>.

Duquia, Rodrigo Pereira, David Alejandro González-Chica, João Luiz Bastos, et al. (2017). “Describing numerical variables: which are the most appropriate parameters to describe the data?”. In: *Anais Brasileiros de Dermatologia* 92.6, pp. 841-843. DOI: 10.1590/abd1806-4841.20174904. <https://doi.org/10.1590/abd1806-4841.20174904>.

Gamble, Carrol, Ashma Krishan, Deborah Stocken, et al. (2017). “Guidelines for the Content of Statistical Analysis Plans in Clinical Trials”. In: *JAMA* 318.23. MOST DEFINITIVE! See supplemental files., p. 2337. DOI: 10.1001/jama.2017.18556. <https://doi.org/10.1001/jama.2017.18556>.

Indrayan, Abhaya (2020). "Reporting of Basic Statistical Methods in Biomedical Journals: Improved SAMPL Guidelines". In: *Indian Pediatr* 57 (1). PMID: 31937697, pp. 43-48.

Marino, Michael J. (2014). "The use and misuse of statistical methodologies in pharmacology research". In: *Biochemical Pharmacology* 87.1, pp. 78-92. DOI: 10.1016/j.bcp.2013.05.017. <https://doi.org/10.1016/j.bcp.2013.05.017>.

Marino, Michael J. (2018). "How often should we expect to be wrong? Statistical power, P values, and the expected prevalence of false discoveries". In: *Biochemical Pharmacology* 151, pp. 226-233. DOI: 10.1016/j.bcp.2017.12.011. <https://doi.org/10.1016/j.bcp.2017.12.011>.

Morey, Richard D., Jeffrey N. Rouder, Josine Verhagen, et al. (2014). "Why Hypothesis Tests Are Essential for Psychological Science". In: *Psychological Science* 25.6, pp. 1289-1290. DOI: 10.1177/0956797614525969. <https://doi.org/10.1177/0956797614525969>.

Olken, Benjamin A. (2015). "Promises and Perils of Pre-Analysis Plans". In: *Journal of Economic Perspectives* 29.3, pp. 61-80. DOI: 10.1257/jep.29.3.61. <https://doi.org/10.1257/jep.29.3.61>.

Petersen, Kristina S, Penny M Kris-Etherton, George P McCabe, et al. (2021). "Perspective: Planning and Conducting Statistical Analyses for Human Nutrition Randomized Controlled Trials: Ensuring Data Quality and Integrity". In: *Advances in Nutrition* 12.5, pp. 1610-1624. DOI: 10.1093/advances/nmab045. <https://doi.org/10.1093/advances/nmab045>.

Schwab, Simon, Perrine Janiaud, Michael Dayan, et al. (2022). "Ten simple rules for good research practice". In: *PLoS Computational Biology* 18.6, p. e1010139. DOI: 10.1371/journal.pcbi.1010139. <https://doi.org/10.1371/journal.pcbi.1010139>.

Simpson, Scot H (2015). "Creating a Data Analysis Plan: What to Consider When Choosing Statistics for a Study". In: *The Canadian Journal of Hospital Pharmacy* 68.4. DOI: 10.4212/cjhp.v68i4.1471. <https://doi.org/10.4212/cjhp.v68i4.1471>.

Sleigh, Jamie (2019). "Is prespecification taking the search out of research?" In: *Pediatric Anesthesia* 29.3, pp. 216-217. DOI: 10.1111/pan.13538. <https://doi.org/10.1111/pan.13538>.

Yuan, Ian, Alexis A. Topjian, Charles D. Kurth, et al. (2019). "Guide to the statistical analysis plan". In: *Pediatric Anesthesia* 29.3, pp. 237-242. DOI: 10.1111/pan.13576. <https://doi.org/10.1111/pan.13576>.

Templates

Downloadable templates developed by the BSC

- [SAP-Outline-E4L.md.txt](#)
- [SAP-Outline-E4L.tex](#)
- [SAP-Outline-E4L.tex.docx](#)
- [SAP-Outline-Gamble.tex](#)
- [SAP-Outline-Nova-Scotia.tex](#)
- [SAP-Outline-statprobe.tex](#)

Links to external .docx and .pdf templates

12+ SAMPLE Data Analysis Plans in PDF | MS Word 12+ SAMPLE Data Analysis Plans in PDF | MS Word. Many sample plans to download. <https://www.sample.net/business/plans/data-analysis-plans/>.

Amsterdam University Medical Centers (2020). *Analysis Plan*. Includes downloadable template. <https://aph-qualityhandbook.org/set-up-conduct/process-analyze-data/3-2-quantitative-research/3-2-2-data-analysis/analysis-plan/>.

Duke Office of Research Initiatives, Duke University *Design the analysis plan*. Links to units at Duke University. <https://myresearchpath.duke.edu/topics/design-analysis-plan>.

Evidence for Learning *Statistical Analysis Plan Template*. Downloadable .pdf template. <https://evidenceforlearning.org.au/research-and-evaluation/evaluation-resources/resources-for-evaluators>.

Institute, Murdoch Children's Research (2020). *Statistical Analysis Plan Template*. Downloadable .doc template. https://mcricfigshare.com/articles/online_resource/Statistical_Analysis_Plan_Template/12606434/1.

Michigan Institute for Clinical & Health Research (MICHHR), University of Michigan (2018). *Statistical Analysis Plan Template*. Sample template for clinical trials. Click 'Access the template' link. File: 'SAP+Template_20180821.docx'. <https://michr.umich.edu/resources/2019/1/17/specimen-core-amp-processing-lab-qampa>.

Office of Population Affairs. U.S. Department of Health & Human Services (2016). *Impact analysis plan template*. Downloadable .docx template. <https://opa.hhs.gov/research-evaluation/evaluation-training-and-technical-assistance>.

Examples

WHO Global Clinical Platform for the Clinical Characterization of COVID-19: Statistical Analysis Plan (2021). *WHO Global Clinical Platform for the Clinical Characterization of COVID-19: Statistical Analysis Plan*. WHO Reference Number: WHO/2019-nCoV/Clinical/Analytic_plan/2021.1. <https://www.who.int/publications/i/item/WHO-2019-nCoV-Clinical-Analytic-plan-2021.1>.

Brown, Michaela, Laura Sutton, and Paula Williamson (2018). *TORPEDO-CF: Trial of Optimal Therapy for Pseudomonas Eradication in Cystic Fibrosis. Statistical Analysis Plan*. Version 2.0. Trial registration: ISRCTN02734162. Eudract No. 2009-012575-10. https://www.uhbristol.nhs.uk/media/3933191/torpedo_final_analysis_statistical_analysis_plan_v2.pdf.

Linsell, Louise, Jennifer Bell, Edmund Juszcak, et al. (2020). *RECOVERY: Randomised Evaluation of COVID-19 Therapy. Statistical Analysis Plan*. Example SAP, 20 pages. Version 1.0. IRAS no: 281712. REC ref: EE/20/0101. ISRCTN: 50189673. EudraCT: 2020-001113-21. https://www.recoverytrial.net/files/recovery-sap-v2-1_2020-12-02.pdf.

Rasmussen, Martin Gillies Banke, Jesper Pedersen, Line Grønholt Olesen, et al. (2020). *The Short Term Efficacy of Reducing Screen-based Media Use on Physical Activity, Sleep, and Physiological Stress and Well-Being in Families With Children - A Randomized Controlled Trial. Data management and statistical analysis plan*. Example SAP, 5 pages. Clinicaltrials.gov ID: NCT04098913. https://classic.clinicaltrials.gov/ProvidedDocs/13/NCT04098913/SAP_000.pdf.

Sahota, Opinder, Ruth Pulikottil-Jacob, Fiona Marshall, et al. (2016). "Comparing the cost-effectiveness and clinical effectiveness of a new community in-reach rehabilitation service with the cost-effectiveness and clinical effectiveness of an established hospital-based rehabilitation service for older people: a pragmatic randomised controlled trial with microcost and qualitative analysis - the Community In-reach Rehabilitation And Care Transition (CIRACT) study". In: *Health Services and Delivery Research* 4.7. Appendix 1: Statistical Analysis Plan by Wei Tan, pp. 1-90. DOI: 10.3310/hsdr04070. <https://doi.org/10.3310/hsdr04070>.

University of Minnesota (2023). *Examples of data management plans*. Examples of data management plans. <https://www.lib.umn.edu/services/data/dmp-examples>.

Zhong, Sam (2019). *Direct Intra-arterial thrombectomy in order to Revascularize AIS patients with large vessel occlusion Efficiently in Chinese Tertiary hospitals: a Multicenter randomized clinical Trial (DIRECT-MT). Statistical Analysis Plan(SAP)*. Example SAP, 41 pages. Protocol Number: CH01. Version Status (Draft /Final / Amendment): 2.0 / Amendment. https://classic.clinicaltrials.gov/ProvidedDocs/06/NCT03469206/SAP_000.pdf.

Blog Posts and Additional Guidance

Blaise, Barche (2020). *How to Create a Data Analysis Plan: A Detailed Guide*. <https://learn.crenc.org/how-to-create-a-data-analysis-plan/>.

Cross Validated (2014). *Resources to write a statistical analysis plan*. Long answer with some useful links. <https://stats.stackexchange.com/questions/118615/resources-to-write-a-statistical-analysis-plan>.

Eisenbeisz, Elaine (2017). *5 (Fairly Simple) Statistical Analysis Plan Elements To Implement In Your Clinical Study*. Topics: Sample Size; Attrition; Analytical Population; Multiplicity; GIGO (garbage in, garbage out - mind your data); SAP after the fact. <https://www.clinicalleader.com/doc/fairly-simple-statistical-analysis-plan-elements-to-implement-in-your-clinical-study-0001>.

Sirisilla, Shrutika (2022). *Effective Use of Statistics in Research – Methods and Tools for Data Analysis*. Not SAP. Mentions 7 or so types of statistical analyses. <https://www.enago.com/academy/statistics-in-research-data-analysis/>.

Sriram, Ramya (2021). *How to Develop a Statistical Analysis Plan (SAP) For Clinical Trials*. On-screen document with links to resources. <https://www.kolabtree.com/blog/how-to-develop-a-statistical-analysis-plan-sap-for-clinical-trials/>.