



Co-Authorship and the Role of the Experienced Biostatistician

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Long-time experience in clinical research has led us biostatisticians to write this document. We work closely together with clinical researchers, and this has resulted in a large number of publications in medical journals with us being co-authors or authors. In contractual collaborations, in which we are paid for data analysis, we are sometimes asked whether we want to be co-authors and whether co-authorship would preclude payment. This document is intended to define our role and give an answer to this question.

Our aim in clinical research is to perform valid statistical analyses. We follow the highest standards regarding reproducibility, e.g. by writing statistical analysis plans prior to the analysis and by creating dynamic reports of methods and results. Dynamic reporting is achieved by connecting the statistical software package R [R Core Team, 2020] with \LaTeX through `knitr` [Xie, 2014, 2015] or R Markdown [Xie et al., 2018, Allaire et al., 2020]. We adhere to reporting guidelines corresponding to study type¹. Senior biostatisticians in our team have at least 15 years of experience, junior researchers have at least two years. On top of planning or performing statistical analyses, we often give substantial input to research questions, feasibility and study design.

Our co-authorship in medical publications based on our analyses guarantees transfer of this quality to the manuscript. Also, data analysis is a substantial intellectual contribution to a scientific paper, and qualifies for authorship according to prevalent guidelines, such as the recommendations of the International Committee of Medical Journal Editors² on Defining the Role of Authors and Contributors [ICMJE: International Committee of Medical Journal Editors, 2020], which are adopted by most medical journals. However, in addition to making a substantial contribution to the work, duties of a co-author are to critically revise the manuscript, to approve the final version, and to be accountable for the accuracy and integrity of all aspects of the work. We take this responsibility seriously, and will be revising intermediate and final versions of manuscripts critically regarding all aspects, not only statistics. In cases where revisions of the statistical methods are required, we will be able to explain, defend, and sometimes adjust the methods we chose.

1 What You Can Expect if We Are Co-Authors

As co-author of your research paper, the biostatistician will write the statistical methods section, will produce publication-ready graphics according to the requirements of the journal, will perform

¹for example STROBE for observational studies, CONSORT for randomised trials or TRIPOD for prognostic studies, see <https://www.equator-network.org/>

²formerly known as Vancouver Group, after the location of their first meeting in Vancouver, British Columbia in Canada.

a thorough review of the manuscript with specific focus on the presentation and interpretation of the results and will take responsibility to answer statistical/methodological reviewer comments. This work on the manuscript is free of charge. To be able to fulfill these duties, we need to receive a draft of your manuscript, to be given time for a critical review and to be asked for approval of the final version before submission. We further need to be informed about the journal's decision and to be asked for approval of revised versions.

2 Mention in Acknowledgments

While mention in the acknowledgment is inappropriate for someone who performed the statistical analysis, it may be appropriate in other situations. However, note that because acknowledgment may imply endorsement of a study's data and conclusions, we need to be informed about potential mention in the acknowledgments of your paper [ICMJE: International Committee of Medical Journal Editors, 2020].

3 Why Payment and Co-Authorship Are not Mutually Exclusive

While co-authorship is related to the intellectual contribution to a scientific paper, payment is not. Please understand that the clinical research we are supporting with methodological support and data analysis usually is not research we would (and could) be conducting ourselves. On the other hand, interest in our biostatistics knowledge and data science is high, and our resources are limited. Since our salaries are partially or fully paid by third party money, receiving payment is necessary for us to be able to deliver this support.

4 References

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