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Evidence and Sincerity - That's What it's All About!

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INTRODUCTION

Treatment of malignant neoplasms is one of the major issues in global health care research. Recent advances in therapeutic, diagnostic, and palliative opportunities enabled patients concerned to prolong their overall as well as disease-specific survival at an acceptable quality of life level. Despite these unmistakable improvements, however, cancer is responsible for so many deaths, which points to the fact that there are still many things we don't know about the disease. One reason is for sure the genesis of malignant tumours is still obscure to date, which is why oncological research comprises so many different areas including in-vitro studies, animal experiments, and studies in the above mentioned fields. Furthermore, determinants for the development of malignancies are captured by epidemiological and genome wide association studies.

According to the broad range of study types and experimental designs in oncological research, specific aspects of statistical analysis has to be considered when planning, conducting, analysing, and interpreting respective data. A major issue in preclinical studies using animals is the question how many animals should be applied in order to ensure reliable findings. However, a general problem in animals studies is the fact that there is hardly preparatory knowledge that could be used within the process of sample size estimation. This has to be taken into account when the results of such studies are to be interpreted.

The planning and analysis of therapy studies in oncology include complex approaches these days. Trials with sequential testing procedures, adaptive sample size calculation plans, and advanced statistical models to analyse the data have been established in recent years. In particular, these methods concern the appropriate handling of time-to-event data including possibly recurrent events. These methods enable a more reliable description of the investigated research question and contribute to the aim of producing evidence-based findings in health care research. Certainly, the application of complex statistical approaches and principles requires sound expertise in the statistical field which cannot be demanded of principal investigators with a medical background. It is therefore all the more important to join expert knowledge in health care research by incorporating distinct scientific fields related to the particular projects.

In order to generate reliable findings in cancer research it is mandatory to conduct high quality studies. Due to the relevance of cancer in global health, novel insights in genesis and treatment of malignant neoplasms are longingly expected. Hence, doubtful results do not put forward oncological research in the desired manner, and this is why there should be put so much emphasis on high quality analyses. But the generation of findings according to the principle of evidence-based medicine does not only involve to apply the most appropriate statistical methods and study designs, it is also important to properly conclude from the results. Specifically, a proper interpretation of p-values requires attention. The question whether the reported p-values in a manuscript have to be interpreted in a confirmative or a rather explorative manner cannot be decided distinctly sometimes. In case of multiple research hypotheses to be investigated by means of one data set it is all the more important to have a decision on that, since p-values with a confirmative interpretation necessitate to adjust the overall significance level according to the number of hypotheses to be tested.

The highest level of information gained from scientific studies is of course grounded on systematic reviews and meta-analyses. They summarize the various results available from single studies in order to provide a final evaluation of

a specific topic of research. Nevertheless, also the merit of a systematic review or meta-analysis has to be critically discussed according to the studies included. If there has been put garbage in, one will get garbage out.

It is the duty of all authors, reviewers, and editors to work, assess, and publish in accordance with the guidance of good clinical practice. High quality results can only be generated by studies implementing high quality methods. It is mandatory to controversially discuss the value and limitations of study results arising from the given conditions. In light of the actually complex analysis methods applied in oncological research partially it is all the more important that authors will provide comprehensive information on the methods used for study design and analysis. Reporting of the results should adhere to established guidelines, like e.g. the CONSORT statement for clinical studies, the STROBE guideline for observational studies, the PRISMA guidance for systematic reviews and meta-analyses, and finally the ARRIVE guidelines for animal studies. Strictly following the respecting checklists will ensure that all important aspects are mentioned within an article, which is worthwhile for both authors and readers.