Grant Advice for Trial Statisticians

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Applying for funding for statistical support within a clinical trial

We strongly believe that a statistician has an important role throughout the life of a clinical trial. In the planning and design stage, statistical input is essential to ensure that the research question is answerable, the study design and plan for data collection are appropriate to address the research question, and the sample size calculation and the analysis are correct. Before the start of the trial, a statistician generates a randomisation list. During the conduct of the trial, issues regularly arise where statistical input is essential to maintain the integrity of the trial, for example regarding data collection and cleaning, participant withdrawal, and protocol violations, making it desirable for a statistician to attend regular meetings with the study team. Also, where applicable, statisticians are involved in Data and Safety Monitoring Boards (DSMB) as the independent DSMB statistician, the independent unblinded statistician preparing statistical reports for the DSMB, and as the study statistician overseeing DSMB processes. Finally, the statistician plays a crucial role in the analysis, interpretation and reporting of the study data.

Given the integral role of the statistician in the trial team, we think it is important that the statistician be a Chief Investigator (CI) on the grant application. This role is usually unfunded and is an oversight role. In addition to this, we advocate for the inclusion of a Personnel Support Package (PSP) for hands on statistical support for the duration of the trial, which would be overseen by the statistical CI.

For a reasonably small, single centre trial, we would recommend requesting 0.1 full-time equivalent (FTE) for the first year during the planning stage of the trial, 0.05 FTE for the middle years during trial

conduct period, and then 0.2 FTE during the final year for analysis and reporting minimum at PSP level 3 as part of the trial budget. Large, multicentre and/or complex trials may require more time than this, say at least twice these FTE recommendations, and minimum at PSP level 4. Example text for the justification for statistical support (study statistician) in a small, single centre, 4-year study is:

> *In year 1 the requested PSP position will be needed to generate the randomisation list, help design the case report forms, help set up the study database, help set up procedures for data management including data checking and cleaning, and writing a detailed statistical analysis plan. In years 2 and 3, the PSP will be required to attend regular study group meetings, monitor the data collection and assist with data checking. Finally in year 4, the PSP position will be required to conduct a full evaluation of the data including data checking, summarising the available data and the statistical analysis of the final trial results. This person will also be involved in the presentation of results both at conferences and in scientific papers on which (s)he will be named as an author. These tasks require considerable time and specialist training in statistics to ensure the quality of the output from this research. The PSP3 level is the minimum at which we could recruit someone with the necessary high-level statistical skills (preferably at Masters level in biostatistics or applied statistics or similar) and depth of experience in trials.*

For clinical trials monitored by a DSMB, a statistician is required to prepare the reports for the committee. The time required for a statistician to prepare these reports should be budgeted for within the grant application in addition to the above.

It should be noted that, in general, a statistician does not set up nor manage the database, and hence the estimates above exclude those activities. Therefore, in addition to requesting funding for statistical support, it is important to request additional funding for database creation and data management, especially in large, multicentre and/or complex trials. The amount of funding required for this will vary depending on the scope and complexity of the study. For a reasonably simple trial, one option can be to include a fixed cost for setting up the database and the data management/data cleaning procedures. As a minimum, this could be in the range of $10,000. For large multicentre or complex trials, you may need to include a cost for database set up and then an ongoing PSP position to assist with data management for the duration of the study. It is important to think carefully about what database requirements there are for the study and how much time will be required for data management for the duration of the study in order to know how this should be budgeted for in a grant.

Applying for funding for methodological research

It can be difficult to obtain funding for methodological research. In particular, it is challenging to sell the clinical relevance and the translational impact of such research. In our experience, when applying for funding for methodological research it is important to hinge the research on applied examples where the research can make a difference. It is also important to include details on how the findings from the research will be disseminated. This needs to be more than simply journal articles and conference presentations. How can you use the findings from your research to directly change practice in the teams that you work in, and more widely?

In terms of what funding to apply for, it is important to consider the different categories of funding. To date members of ACTA STInG have received funding for methodological research in the form of project grants, fellowships and centres for research excellence. In all of these streams, we have emphasised the clinical impact of the research, and have stressed the importance of conducting biostatistical research in order to remain on the forefront of medical research and to make the most of the vast amounts of data that are collected from applied research projects.

Selling a statistical track record

Working as a biostatistician often means working as part of a number of different teams to address a variety of applied research questions. This mean that biostatisticians often do not have a large number of first author publications and have very few, if any, grants as primary chief investigator (CIA), because both of these are generally led by the applied researcher. This can make it very difficult to have a competitive track record when applying for future grants, either as a CI on an applied or statistical project, or for a fellowship.

When writing a track record as a CI on an applied grant it is important to explain that as a biostatistician you are responsible for the statistical aspects of the studies that you are/have been involved with. For example:

> *My role in my previous successful grants was to assist in the development of the research question and study design, and to take responsibility for the statistical aspects of the proposal. All of these grants included a fraction of salary for statistical support which I am now managing.*

It can also be useful to explain why you have a limited number or no first author publications. For example:

> *As a research biostatistician there is a trade-off between developing a personal portfolio of methodological research, and providing leadership on statistical and related methodological issues in collaborative projects, which results in co-authored publications. This means that a large number of my publications are co-authored papers as opposed to first authored papers. Of note, on X of my co-authored publications I am 2nd or 3rd author reflecting the critical input I have provided as an analytic expert in empirical research.*