

## Guidelines for the content of statistical analysis plans in clinical trials

A group of experts has prepared, tested, and published a list of 55 items/sub-items as guidance for preparing a Statistical Analysis Plan (SAP) for clinical trials.<sup>1</sup> The researchers conducted a survey of current practice across trial units registered with the UK Clinical Research Collaboration and used a Delphi survey to collect information from 73 invited participants including statisticians, guidelines authors, and journal editors. This was followed by a consensus meeting. No existing guidance for SAP content was identified in their literature search or contacts with funders and regulators. The SAP is not a stand-alone document but rather should be read in conjunction with the clinical trial protocol; the protocol should be consistent with the principles of the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement. According to ICH E9 (Statistical Principles for Clinical Trials), a



SAP “contains a more technical and detailed elaboration of the principal features of the analysis described in the protocol, and includes detailed procedures for executing the statistical analysis of the primary and secondary variables and other data”.

The 55 items/sub-items are listed under six sections: Title and Trial Registration; Introduction; Study Methods; Statistical Principles; Trial Population; and Analysis. The supplementary online content has additional information and examples for each item. Some journals,

including *JAMA*, require the SAP to be submitted along with the report of a clinical trial for use within the peer-review process.<sup>2</sup>

### References

1. Gamble C, Krishan A, Stocken D, Lewis S, Juszczak E, Doré C, et al. Guidelines for the content of statistical analysis plans in clinical trials. *JAMA*. 2017;318:2337–43.
2. DeMets DL, Cook TD, Buhr KA. Guidelines for statistical analysis plans. *JAMA*. 2017;318:2301–3.

## Authorship policies in an age of large research teams

A five-page editorial authored by *JAMA* editors explains their policy for maintaining integrity of authorship in team science.<sup>1</sup> Their concern is that as science has become increasingly collaborative, it is becoming more common for papers to have hundreds or even thousands of listed authors. They gave examples of papers on the sequencing of the human genome with 270 authors and 240 listed as collaborators. In their editorial, they have reproduced the *JAMA* Network journals authorship form. Authors must comply with the four ICMJE (International Committee of Medical Journal Editors) criteria. Individuals who do not meet authorship criteria but who have made important substantive contributions to the work should be acknowledged for their contributions and can be listed as collaborators. The main headings of the editorial are: author and research group designations; other authorship considerations (author contributions, shared author responsibilities, changes in authorship, resolving disagreements among authors). The following terms and definitions are listed:

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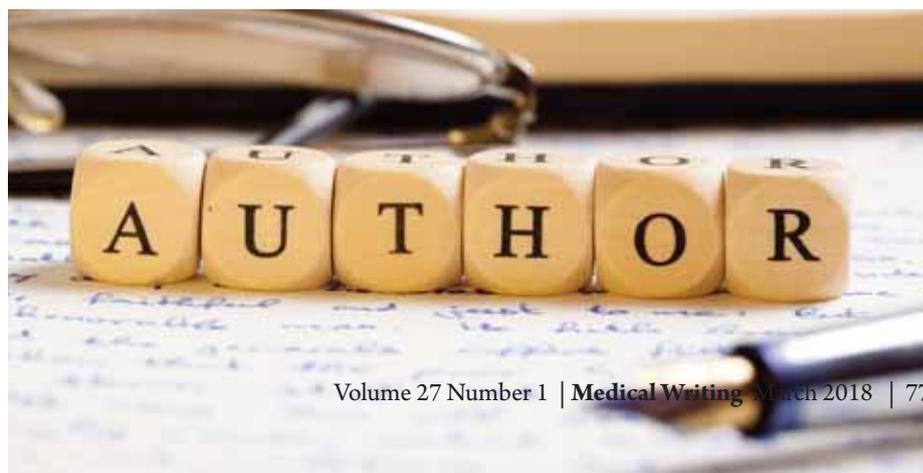
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### Reference

1. Fontanarosa P, Bauchner H, Flanagin A. Authorship and team science. *JAMA*. 2017;318:2433–7.



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