NO-PROFIT CLINICAL TRIALS COMPLIANCE WITH SPIRIT GUIDELINES

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Introduction

The SPIRIT 2013 Statement provides evidence-based recommendations for the minimum content of a clinical trial protocol. SPIRIT is widely endorsed as an international standard [1]. It consists of a checklist of 33 items and a figure, and is accompanied by an explanation and elaboration document containing relevant details for each item. After 10 years from its publication, many are still unaware of its usefulness when preparing protocols of clinical trials to be submitted to the Ethical Board (EB). Following such guidelines ensures clarity, quality and feasibility of clinical trials [2]. Items 18-21b concentrate on the statistical and epidemiological aspects.

Objectives

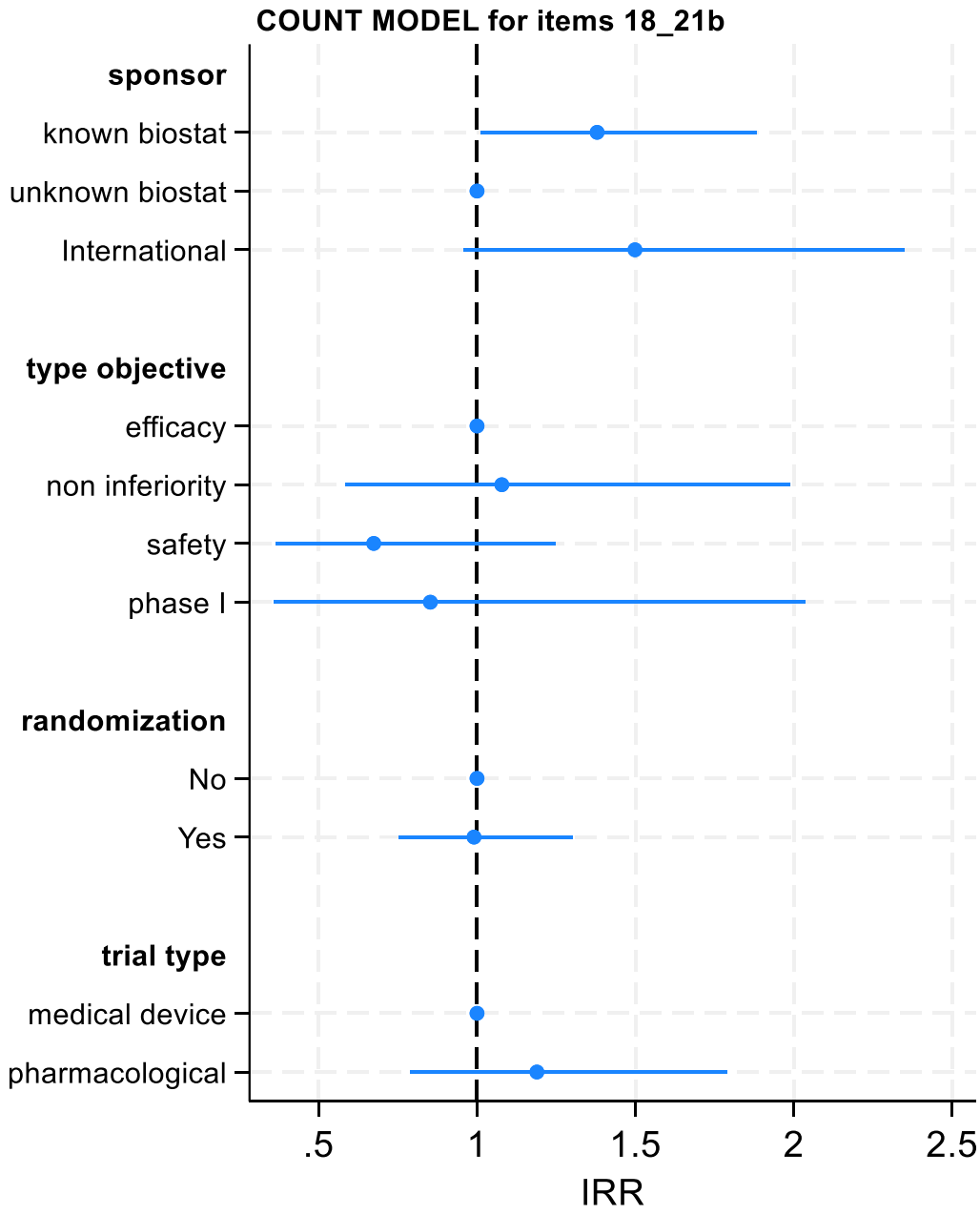
We aimed at analysing such protocols to assess the rate of adherence to the SPIRIT guidelines and its potential correlates, particularly in all those items that would benefit from the collaboration with a biostatistician (items 18-21b).

Methods

We retrieved information on design and methodology of no-profit protocol submitted in years 2021-2022 to the local EB. We used the SPIRIT checklist to identify the proportion of items that were satisfied for each study. We computed the median with interquartile range (IQR) of such proportions over all studies. Due to overdispersion, a negative binomial regression models was fitted. The potential correlates of the number of satisfied items were: type of sponsor (San Matteo Hospital vs other Italian Institution vs International), randomisation, type of trial (pharmacological vs other) and main objective of the study (efficacy, non-inferiority, safety, phase I). We use the Stata software (release 17), for all analyses.

Results

Seventy clinical trials are analysed. The Fondazione IRCCS Policlinico San Matteo sponsored 20 trials (29%); other Italian Centres sponsored 45 (64%) studies while 5 studies (7%) had an international sponsor. Twelve protocols (17%) were single centre, the remaining 58 being multicentre (60% national and 7% international). Forty-four studies (63%) were designed as randomized trials. The median percentage of satisfied items in methodology (items 9 to 21b), was 72% (IQR 50%-83%). However, for collection, management and statistical analysis (items 18-21b), the median percentage of correctly satisfied items was 56% (IQR 50%-83%). Though overall, the model p-value was 0.54 (LR Chi2 5.98), some signal was elicited that institutions with a Biostatistics Unit might have higher adherence to SPIRIT (number of satisfied items among 18-21b) with respect to other national institutions, which possibly did not have this type of facility (IRR 1.38 , 95%CI 1.01-1.88, Figure); for international studies we estimated an IRR of 1.50, 95%CI 0.96-2.35.



Conclusions

Although many of the studies analysed followed the SPIRIT guidelines at least partially, more attention is needed to identify potential modifiable factors in order to increase the adherence to the guidelines for quality research. Our results suggest that a biostatistical unit has a relevant role in favouring adherence to SPIRIT, though a larger study is needed for confirmation. Results updated to 2023-Q2 will be presented.

Keywords: Spirit Guidelines, Quality Research, Clinical Trial.

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