

Award Title: R44 Impact Increasing the impact of the Statistical Analysis Plan guidance.

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Budget: £3,600

Final spend: £2950.22

Award objectives and achievements:

- **Downloadable version of the checklist**

A downloadable version of the checklist and elaboration document has been hosted on the Liverpool Clinical Trials Centre website in order to monitor rate of access. Links to the documents hosted on the LCTC website have been added to the SAP page on the Equator Network website and circulated using social media and TMRP partner newsletters.

- **Endorsement by key journals**

The BMJ, Trials, PLOS One and Clinical Trials were initially contacted to discuss recommendations to their authors to follow the guidance and submit SAPs. Whilst the BMJ already mandated SAP submission for manuscripts reporting randomised control trials (RCTs), their publication policy now references the guidance (www.bmj.com/about-bmj/resources-authors/article-types). Trials has co-authored an editorial encouraging SAP submission highlighting the different publication options. The editorial which references the guidance should be published shortly having been uploaded to their manuscript management system on the 5th March 2020. However, Trials were not willing to mandate SAP submission due to limited peer review resources. PLOS One, although supportive were not willing to endorse and Clinical Trials did not respond to our correspondence.

Due to the mixed response we undertook a review of the major medical journals' RCT publication policies to understand what is deemed mandatory. They all require SAP submission alongside RCT manuscripts, but the rate of publication varies [1]. This is driven by ICMJE guidance which encourages editors to review protocols and SAPs and to make these publically available [2]. Consequently, we plan to use the ICMJE mandate to provide a more compelling argument to use the SAP guidance within peer review. Initially we will approach members of ICMJE we have not previously contacted (e.g. The Lancet, NEJM, Annals of internal Medicine and JAMA) before approaching other journals that subscribe to ICMJE guidelines and publish clinical trial reports. JAMA is included in this list because despite publishing the original manuscript they do not seem to have adopted it into their publication policies.

- **Increasing citation of the guidance by funders and other organisations.**

The Wellcome Trust were contacted and have agreed to reference the guidance in the next update of their RCT policies which are planned for summer 2020. A review of NIHR's RCT policy has been undertaken and contact has been made with Ensuring Value in Research (EVIR) to discuss funders' perspectives on how to increase the uptake of the guidance.

- **Citation Analysis**

A citation analysis of the original guidance published in JAMA on 19th Dec 2017 was undertaken on 11/02/2020 using Web of Science and Google Scholar. The guidance was cited as being used as a template in 5 SAPs and 1 study report in 2018, 8 SAPs in 2019 and 3 SAPs published in 2020 by the time of analysis. First authors were located in the UK, Canada,

USA, China, Chile, Saudi Arabia, Finland and Germany. In addition, a further 6 protocols cited the guidance stating they would develop a SAP in line with the recommendations. Sixty-two citations were identified in total with the remaining papers citing the guidance for a variety of reasons including justifying a statistical approach, discussing transparent reporting and methods for developing other guidelines.

Impact (data correct as of 23rd March 2020)

- A short presentation of the current uptake of the SAP guidance and our dissemination activities was presented at the REWARD EQUATOR Network 2020 conference in Berlin on 21st February 2020.
- The SAP webpage on the LCTC website was accessed internationally 477 times since the 12th November 2019. Download tracking was enabled on the 12th December 2019 and shows 97 downloads of the checklist and 47 downloads of the elaboration document.
- A social media post on the 16th January sharing details of the downloadable checklist generated 4344 impressions and 48 link clicks. The post was retweeted 14 times by several key organisations and individuals with large numbers of followers.
- The SAP guidance has now been referenced in:
 - The BMJ's RCT publication policy (<https://www.bmj.com/about-bmj/resources-authors/article-types>)
 - The Center for Open Science resources list (<https://osf.io/kgnva/wiki/Open%20Science%20Literature/>)
- The SAP guidance will be added to the next revision of the Wellcome Trust Clinical Trials Policy and Outputs Management guidance (Scheduled for summer 2020)

Next steps

- Communication with NEJM, JAMA, The Lancet, ECRIN and pharmaceutical industry organisations such as ABPI and PSI.
- Continue to pursue meetings with key organisations like EVIR to gain broader support and identify means of increasing uptake of the guidance.
- Co-authors of the SAP guidance, the TMRP Statistical Analysis Working Group and other members of TMRP are in the process of being contacted to try and identify different avenues for promoting the guidance especially internationally.
- Information to be included in the Society of Clinical Trials newsletter.
- NIHR have funded an extension of the guidance for early Phase Trials. Professors Gamble and Stocken (Leeds CTRU) are collaborating on the project.

References

1. Spence, O. *et al.* (2020) 'Availability of study protocols for randomized trials published in high-impact medical journals: A cross-sectional analysis', *Clinical Trials*, 17(1), pp. 99–105.
doi: [10.1177/1740774519868310](https://doi.org/10.1177/1740774519868310).
2. WHO joint statement. <https://www.who.int/ictcp/results/jointstatement/en/index1.html>
Accessed 18th February 2020.