**Summary of qualitative feedback on round 2 of Delphi exercise for CONSORT extension for adaptive trial designs**

**Checklist item 1a - Title**

Six participants provided additional comments on checklist item 1a. Two participants queried whether it was important to identify the trial as adaptive in the title. Another suggested that it was important to define what is classed as a publication, recommending that the word adaptive should be used across trial registries, published protocols and the results paper. In addition to this, one participant queried the broader issue about how to describe a trial using minimization, as opposed to randomisation. Two participants simply stated their support for this item.

**Checklist items 1b-1f - Abstract**

A total of nineteen participants provided feedback on the proposed extension to abstracts for adaptive trials. Four participants expressed concern at the feasibility of including material on all items in the abstract, despite recognition of the importance to adaptive trial designs and a particular item (1e: adaptation decisions) was queried by a further six participants given word count restrictions for abstracts. Clarifications to item 1c were suggested by two participants to state ‘primary outcomes and intermediate outcomes, if necessary’ as opposed to presenting this as a choice between the two. Four participants queried the content of item 1d, and the need to include interim results in the abstract was questioned. The other comments from participants highlighted the importance of advising researchers on how to report adaptive trials; ensuring that key information on the type of adaptive design is given and clearly describing the use of Bayesian methods in the abstract, where relevant.

**Checklist items 2a and 2b – Background and objectives**

Two participants provided additional comments on these checklist items. One highlighted the importance of their inclusion in trial reporting and the other suggested that this section should specify why an adaptive design was used, despite this material being address in section 3.

**Checklist items 3a-3e – Methods: Trial design**

Twelve participants provided additional comments on these adapted/new checklist items. There were several comments on item 3e (adaptive design properties) including: simplifying this item to reword it for comprehension; that a reference to another paper would be sufficient for ‘well known’ designs; and adding simulation results to an annex to control type I and type II error rate of adaptations. Two participants suggested that the adaptive design properties and discussion of unplanned changes could also be covered in the discussion section. One participant suggested that 3a and 3d (description of trial design and unplanned changes) were less important to them as they felt the focus in this section should be on the type of adaptive design used, whereas another stated that ‘[a]s a statistician, I find that all these items are crucial for reliable reporting’. Finally, one participant highlighted the importance of presenting this section clearly to help support investigators who need clear instructions.

**Checklist items 4a and 4b – Methods: Participants**

**Checklist item 5 – Methods: Interventions**

No additional comments were made on these sections of the checklist that were relevant to their extension to adaptive designs.

**Checklist items 6a and 6b – Methods: Outcomes**

Five participants provided additional feedback on these checklist items, but only two comments were of substance. That is, one suggested that although 6a could include pre-specified primary and intermediate outcomes, it could also work if a strong rationale for not including this in the reporting were given. The other participant suggested that this material was not essential and they would be happy for the content for these items to usually be placed in supplementary material.

**Checklist items 7a and 7b – Methods: Sample size**

Eight participants provided additional feedback on these items; on the one hand expressing strong support for their inclusion in the extension and on the other concern at the feasibility of covering the material in a standard journal article word limits, and suggesting that this could be adequately addressed in the SAP or protocol.

**Checklist items 8a-8c – Methods: Randomisation sequence generation**

Four participants provided additional comments here to express concern about revising ‘well established required items’ in the checklist, ensuring that the appropriate level of detail is included is key for these items; the importance of determining how to deal with trials using minimization. Specifically, one participant commented on the importance of 8c, suggesting that this read more like the results of an adaptive trial rather than preplanned adaptation rules.

**Checklist item 9 – Methods: Randomisation allocation concealment mechanism**

**Checklist item 10 – Methods: Randomisation implementation**

No additional comments were made on these sections of the checklist that were relevant to their extension to adaptive designs.

**Checklist items 11a-11c – Methods: Blinding**

Five participants commented on this section. One participant queried which issues should be covered in terms of confidentiality by checklist item 11c, suggesting that this should be made clearer. Interestingly, another participant commented on the spread of results in round 1 to suggest that these reflect the ‘varied orientations of all stakeholders’. To demonstrate this, they and another participant both highlighted how this is not something that they are particularly concerned about. Conversely, another participant highlighted how this is crucial to the acceptance of adaptive designs by sponsors and improving blinding would be of benefit to the wider scientific community.

**Checklist items 12a-12g – Methods: Statistical methods**

Thirteen participants provided additional comments on the checklist items in this section. Some general comments included: it would be useful to check the discussion of the estimand from the revised ICH-E9; acknowledgement of the importance of transparency of reporting statistics for adaptive trials; yet others queried whether some of the analytical details may be better presented in a supplementary appendix and a measured approach to reporting the details of statistical methods should be taken, only where appropriate. However, one participant highlighted the lack of guidance on how to determine appropriateness as a limitation. More specifically, two participants were confused by 12c and why this was separate to 12a and 12b. The specificity of items 12c, 12d and 12g was questioned. In relation to 12c, one participant suggested that the material in parenthesis should be deleted to broaden applicability, and reduce the focus on bias. For 12d, one participant suggested that this is specific to a very narrow set of methods and including this requirement begs the question why other methods are not represented in the same way in the checklist. Another participant queried how the decision on the appropriateness of reporting would be made for 12f. There were several comments on 12g: that prior probability distributions are only necessary for Bayesian designs; the item is too specific and should be dropped or clarify that only where applicable.

**Checklist items 13a and 13b – Results: Participant flow**

Two participants queried the necessity of extending checklist item 13a on the grounds that this was seen to be redundant and sufficiently covered in the standard CONSORT checklist.

**Checklist items 14a-14c – Results: Recruitment**

Nine participants provided additional comments on the checklist items in this section. Four of these comments were just generally supportive of their inclusion in the adaptive design extension, and a fifth was inconsequential to the extension of the checklist. The wording of 14a was queried by two participants to suggest that this should read ‘with reasons’, as opposed to ‘and reasons’ as per the current drafting. Two participants commented on 14b: one to suggest that it should be extended to explain why the whole trial or elements of the trial (treatment arms) were stopped, and another highlighted that this is particularly important if they relate to difficulties of setting up an adaptive design to help others wanting to adopt this methodology. One participant refused to score 14c on the grounds that some trials with adaptive design have too many adaptations to cover in the main paper, and suggested that summarizing how the adaptation played out would be sufficient and more detailed information could be presented in an appendix.

**Checklist items 15a and 15b – Results – Baseline data**

Nine participants provided additional feedback on checklist items relating to baseline data. Mixed views were expressed on the utility of baseline data to interpret trial results (15a). The comments on the new item about similarity/representativeness of patient population by interim stage mostly expressed concern at the necessity and feasibility of always reporting this.

**Checklist item 16 – Results: Numbers analysed**

There was only one substantive comment on this checklist item, to caution that this only makes sense for simple designs and it is important that the extension can also apply to the more innovative designs which will have ‘dozens’ of interim updates.

**Checklist items 17a-17c – Results: Outcomes and estimation**

Seven participants provided additional comments on 17a and 17c to mostly query whether its necessary to include results for each interim analysis and decision, and suggested that most of these could be presented in the supplementary material. One participant expressed concern about the applicability of these items to more innovative designs (as above with checklist item 16).

**Checklist item 18 – Results: Ancillary analyses**

**Checklist item 19– Results: Harms**

**Checklist item 20 – Discussion: Limitations**

**Checklist item 21 – Discussion: Generalisability**

No additional comments were made on these sections of the checklist that were relevant to their extension to adaptive designs.

**Checklist items 22a and 22b – Discussion: Interpretation**

Eight participants provided feedback on the extension to the new checklist item 22b. Whilst they acknowledge the importance of this information on how the research contributes to future adaptive designs, queries were raised about the feasibility and necessity of including this material in the main paper, not least because this is not a requirement of the standard CONSORT. Several participants suggested that this should be addressed in a methodological paper or supplementary material.

**Checklist item 23 – Other information: Registration**

No additional comments were made on this section of the checklist that were relevant to its extension to adaptive designs.

**Checklist items 24a-24f – Other information: Trial documentation**

Thirteen participants provided additional feedback on the checklist items in this section. Numerous general comments on the necessity of having the simulation protocol, data monitoring charter and statistical code relating to suggestions that these items should be encouraged, rather than mandated (and available on request) ‘in the hope of incentivizing good practice in the medium term’. The burden on journal reviewers should also be considered when weighing up the benefits of extending this checklist item. One participant put this simply, and suggested that 24c-24f could be covered as a single item under 24b. Most specifically on 24c, there were several suggestions, which included: clarifying that provision of the SAP is not optional, only where full details are not given in the protocol, giving the option for this to be provided as an appendix to support academic centres with limited budgets for open access publication.

**Checklist item 25 – Other information: Funding**

No additional comments were made on this section of the checklist that were relevant to its extension to adaptive designs.