CTU Name: _____

Details of statistics representative who completed this survey:

Name: _____

Email: _____

We ask the above details for the purposes of keeping a record of responders and to ascertain aggregate data regarding survey completion. If you do not wish to be acknowledged for your participation, please tick here: ☐

Please return the completed surveys to V.S.Homer@bham.ac.uk.

The following questions are about Statistical Analysis Plans (SAPs) and current practice within your CTU. We would also be grateful if your responses could be made on behalf of your CTU, so it may help to discuss the survey with your colleagues before returning it.

For the purpose of this project and survey, we are defining early phase trials as trials which aim: to determine safe doses and dosing schedules for a treatment/intervention (phase I), or whether or not there is any signal of efficacy for that intervention (phase II or I/II).
Our definition therefore includes single-arm or randomised phase I trials and single-arm phase II trials such as:

- Rule-based phase I trials (such as the 3+3 design),
- Model-based phase I trials (such as the continual reassessment method),
- Model-assisted phase I trials (such as modified toxicity probability interval (mTPI) design),
- Randomised dose finding phase I trials (such as those which randomise between placebo and a dose of the experimental treatment, or those which randomise to attain the optimal doses or dose schedules once safety has been assured),
- Single arm phase II trials.

Does your trials unit run early phase clinical trials?

Yes ☐ No ☐

If you answered no to the above question, we would appreciate it if you could return the survey with only this question answered using the details provided at the start. We would like to thank you for your time in reviewing our request and shall no longer contact you in relation to this project.

If your unit does run early phase clinical trials, we would greatly appreciate it if you could complete the remainder of this survey.

1. Regardless of trial phase, does your trials unit have a SAP template, or a specific set of instructions, that you use when authoring SAPs?

Yes ☐ No ☐

1a. If no, reason why? Please tick one:

Template is not required ☐

Please specify why _____

Template under development ☐

Need for template recognised but development has not started ☐

Other (please specify) _____

2. When authoring SAPs for early phase clinical trials, as defined at the start of this document, which of the following is most appropriate:

a. we have a specific SAP template (or set of instructions) for early phase clinical trials ☐
b. we have a SAP template (or set of instructions) that is applicable to all phases of trial ☐
c. we do not have a template (or set of instructions) for writing a SAP for an early phase clinical trial ☐

2i. If you selected option b, does this template have a specific early phase section?

Yes ☐ No ☐

2ii. If you selected option c, please briefly explain why

3. Are there any scenarios of early phase trials where you would **not** produce a SAP?

Yes ☐ No ☐

3a. If yes, for which types of early phase trials would you produce or not produce a SAP for? (If you do not perform these studies at your CTU then please select N/A). Please tick all that apply.

	Would produce	Would not produce	N/A
Rule-based phase I trials	☐	☐	☐
Model-based phase I trials	☐	☐	☐
Model-assisted phase I trials	☐	☐	☐
Randomised phase I trials	☐	☐	☐
Single arm phase II trials	☐	☐	☐
Other (please specify)	_____		

4. What analyses is the produced SAP(s) pertinent for:

Final analyses	Yes ☐	No ☐
Interim analyses	Yes ☐	No ☐
DMC/TSCs	Yes ☐	No ☐
Other (please specify)	_____	

5a. Would you be willing to provide a copy of the template used when writing SAPs for early phase clinical trials to contribute to the project as part of a review of UK CTU practice?

Yes ☐ No ☐

If yes, please forward along at the same time as returning this survey.

5b. Would you be willing to provide an example of an early phase SAP to contribute to the project as part of a review of UK CTU practice?

Yes ☐ No ☐

If yes, please forward along at the same time as returning this survey.

6. Do you think there is a requirement for early phase SAP guidance?

Yes ☐ No ☐

7. If such guidance existed, is this something you feel you would use at your CTU?

Yes ☐ No ☐

As part of this project, we will be producing guidelines, piloting them and holding consensus meetings. If your CTU would be happy to be involved with this project and be contacted in collaboration with it, please nominate a contact and provide their details below.

Name _____

Email _____

If you have any additional comment about SAPs for early phase trials, please use the space provided.

We would like to thank you for the time taken in considering our request and completing this survey. The opinions and views of your CTU are important for this project, and we are grateful for your support.