< Insert trial logo>

**<Insert trial name>**

Trial Steering Committee Charter

Version No.: <insert number> Version Date: <insert date>

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| **EudraCT Number:**  |  | <Insert EudraCT number> |
| **Sponsor Number:** |  | <Insert Sponsor number> |

* All sections in yellow should be deleted prior to circulation and finalisation.
* The charter should reflect the content of the most recent version of the trial protocol and the discussion held with the JRES representative.
* Amend St George’s, University of London to the trust name if the trust is the sponsor
* If the DMC will be reviewing unblinded data then the wording of page 11 and 12 should be changed to reflect this and to describe who will be providing the secretariat for such DMC meetings.

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| *1. Introduction* |
| *Objectives of trial, including interventions being investigated* | ***Title:******Intervention:******Primary outcome measure:*** ***Secondary outcome measure(s):***  |
| *Outline of scope of Charter* | *The purpose of this document is to describe the membership, terms of reference, roles, responsibilities, authority, decision-making and relationships of the Trial Steering Committee (TSC) for the <insert trial name> trial, including the timing of meetings, methods of providing information to and from the TSC, frequency and format of meetings and relationships with other committees.* |
| *2. Membership*  |
| *Membership and size of the TSC*  | *TSC membership will include:* * *Independent chair: <insert name of chair>*
* *<Insert the names of the TSC members>*
 |
| *Whether members of the TSC will have a contract*  | *Members of the TSC will not formally sign a contract but should formally register their assent to join the group by signing the signature page at the end of this Charter. By signing they confirm that they agree to join the TSC, agree to treat all sensitive trial data and discussions confidentially, agree with the contents of the Charter, and agree to follow the instructions as captured in the Charter.* ***Please Note:*** *Any competing interests should also be declared on the signature page.*  |
| *3. Meetings*  |
| *Expected frequency of TSC meetings* | *<Insert expected frequency of meetings>* |
| *Whether meetings will be face-to-face or by teleconference* | *Meetings may take place by teleconference, webex or face-to-face depending on the preference of members (amend as appropriate).* |
| *How TSC meetings will be organised* | *The Trial Office, based at St George’s University of London will provide a secretariat to the TSC. They will organise meetings, assist the Chair in the preparation of a suitable agenda and minute meetings. A copy of the minutes will be filed in the Sponsor’s Trial Master File (amend as appropriate).*  |
| *4. Authority* |
| *Who has ultimate authority?* | *The Sponsor has ultimate legal responsibility for the conduct of the trial. The TSC will make recommendations to the Sponsor. The ultimate responsibility rests with the Sponsor.*  |
| *To whom will the TSC report their recommendations/decisions* | *The TSC will feedback to the Sponsor with its recommendations and decisions.* |
| *What will be done if there is a disagreement between the TSC and the TMG* | *The* Sponsor *has ultimate responsibility for the trial. The Regulatory Assurance Manager acts as the Sponsor’s representative. The TSC will report their recommendations to the Sponsor. The Sponsor should report to the TMG and then report to the TSC on how the TMG have acted upon the TSC’s recommendations. If the TSC has serious problems or concerns with the TMG’s decision, a meeting of the TSC and TMG should be held. The information presented would depend upon the action proposed and the TSC's concerns. The meeting should be chaired by a senior member of the sponsor’s staff or an external expert who is not directly involved with the trial. Depending on the reason for the disagreement, confidential data will often have to be revealed to all those attending such a meeting.**The TSC will assume primacy over the DMC or Chief Investigator.* |
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| *5. Roles and responsibilities* |
| *What is the role of the Trial Steering Committee*  | *The role of the TSC is to provide* ***independent*** *oversight of the conduct of the trial on behalf of the Sponsor and to ensure that the trial is conducted appropriately.* * ***Progress of the trial***

*Monitor the progress of the trial to maximise the chances of completing it within the timescale agreed. Recruitment targets will be monitored at each meeting. The TSC may make recommendations on how to improve recruitment.** ***Amendments to the protocol***

*The TSC may recommend amendments to the trial protocol if they identify an area of concern. They may be asked to review and comment on other amendments.** ***Adherence to the protocol***

*The TSC should review adherence to the trial protocol (for example return of case report forms, deviations and serious breaches) and highlight any areas for concern.* * ***Patient safety***

*In all the deliberations of the TSC the rights, safety and well-being of the trial participants are the most important considerations and should prevail over the interests of science and society. The TSC will discharge its safety role to the Data Monitoring committee who will review the safety data being generated during the course of the trial. If the TSC feel that patients are being put at risk they should immediately notify the Sponsor and the DMC. The notification should be accompanied by a recommended appropriate course of action to ensure patient safety. The TSC will assume primacy over the DMC or Chief Investigator.** ***Consideration of new information***

*The TSC should consider new information relevant to the trial including the findings of other studies, and competing trials.* * ***Recommendations***

*To consider recommendations of the Data Monitoring Committee &/or Ethics Committee. On receipt of any relevant information, the TSC should recommend appropriate action, such as changes to the trial protocol, additional patient information or prematurely terminating or extending the trial. It is the responsibility of the CI and the Chairman and other independent members of the TSC to bring to the attention of the TSC any results from other studies that may have a direct bearing on the future conduct of the trial.* |
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| Members of the <Insert trial name> TSC  | **Trial Steering Committee**<Insert member names> |
| When the TSC is quorate for decision making | Every effort should be made for all members to attend. The secretariat will try to ensure that a date is chosen to enable this. It is expected that the majority of meetings will be via teleconference. If, at short notice, any member cannot attend then the TSC may still meet if at least the chairman and <insert figure> other member(s) is present. If the TSC is considering recommending major action after such a meeting the TSC Chair should talk with the absent member(s) as soon after the meeting as possible to check they agree. If they do not, a further meeting should be arranged with the full TSC. |

The avoidance of any perception that members of a TSC may be biased in some fashion is important for the credibility of the decisions made by the TSC and for the integrity of the trial.

Possible competing interests should be disclosed. In many cases simple disclosure up front should be sufficient. Otherwise, the (potential) TSC member should remove the conflict or stop participating in the TSC. Below are examples of interests that might compete. Depending on the nature of the interest, this will not necessarily exclude you from membership.

## Potential competing interests

* You or your partner have stock ownership in any commercial companies involved in the trial
* Stock transaction in any commercial company involved (if previously holding stock)
* Consulting arrangements with the Sponsor or their representative
* Career success determined by a product or technique assessed by trial
* Intellectual conflict e.g. strong prior belief in the trial’s experimental arm
* Involvement in regulatory issues relevant to the trial
* Investment (financial or intellectual) or career tied up in competing products

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| **No,** I have no competing interests to declare |  |
| **Yes,** I have competing interests to declare (provide details below) |  |

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###  Initial to agree

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| I have read, understood and agree with the <Insert trial name> TSC Charter version ….. dated …….. |  |
| I agree to join the Trial Steering Committee for this trial  |  |
| I agree to treat all trial documentation, data and discussions confidentially |  |

## Important: Data Protection Act

In providing this information you agree for your contact details to be retained by St George’s University of London. This database is used to coordinate the <Insert trial name> Trial.

During the course of the trial we may be required to pass your details onto official bodies such as funders, Research Ethics Committee or MHRA.

Under the requirements of the Data Protection Act 1998 St George’s, University of London must make any records pertaining to you available upon written request. To do so please contact Legal Services at St George’s, University of London. Your details will be kept indefinitely. Your records are regularly reviewed and updated. If you find any of your details are incorrect, please contact the Sponsor Office via researchgovernance@sgul.ac.uk

Print name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: DD / MM / YYYY

**Please return this form to** <Insert relevant information>

Appendix 1: Trial Summary

Appendix 2: Schedule of Events

Appendix 3: Abbreviations and Glossary of Terms