<Insert trial logo>

**<Insert trial name>**

Data Monitoring Committee Charter

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

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

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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 Data Monitoring Committee (DMC) for the <insert trial name> trial, including the timing of meetings, methods of providing information to and from the DMC, frequency and format of meetings and relationships with other committees. | |
| 2. Membership | | |
| Membership and size of the DMC | The DMC will include:   * Chairperson <Insert chairperson name> * <Insert member names> | |
| Whether members of the DMC will have a contract | Members of the DMC 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 DMC, 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 DMC meetings | The DMC will meet <insert relevant information>.  DMC meetings should be scheduled prior to planned TSC meeting to allow the Chair of the DMC to report to the Chair of the TSC (amend if appropriate). | |
| 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 if appropriate). | |
| How DMC meetings will be organised | The <insert trial name> study team, based at St George’s University of London will provide a secretariat to the sessions of the DMC reviewing blinded data. They will organise meetings, assist the Chair in the preparation of a suitable agenda and minute meetings. The DMC chair should chair and minute meetings reviewing unblinded data. These meetings will be organised by the <insert trial name> study team. A copy of DMC meeting minutes will be filed in the Sponsor’s Trial Master File immediately following a meeting reviewing unblinded data or at the end of the study for meetings reviewing blinded data. | |
| 4. Authority | | |
| Who has ultimate authority? | The Sponsor has ultimate legal responsibility for the conduct of the trial. The DMC will make recommendations to the TSC who will in turn make recommendations to the Sponsor. The ultimate responsibility rests with the Sponsor. | |
| To whom will the DMC report their recommendations/decisions | The DMC will feedback to the TSC and Sponsor with its recommendations and decisions. | |
| **5. Roles and responsibilities** | | |
| **What is the role of the DMC** | The role of the Data Monitoring Committee is to monitor accumulating data from the trial at pre-specified intervals, in particular in relation to safety and/or efficacy\* and to make recommendations to the TSC regarding any safety issues that should be brought to the attention of investigators or any ethical reasons why the trial should not continue.  The DMC will be the only group with access to the unblinded data during the course of the trial. (Reword if necessary)  The chair of the DMC will report to the chair of the TSC.  \*delete as appropriate | |
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**Data Monitoring Committee Agreement Form**

The avoidance of any perception that members of a DMC may be biased in some fashion is important for the credibility of the decisions made by the DMC 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) DMC member should remove the conflict or stop participating in the DMC. 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> DMC Charter  version …. dated ………. |  |
| I agree to join the Data monitoring 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 funder’s, 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](mailto:drolfe@sgul.ac.uk)

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

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

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