***The red text in this document is instructional and should be removed prior to the submission of your report****.*

*General guidance on completion of this report:*

* *Sections should not be removed*
* *Sub-headings can be added for clarity*
* *When using abbreviated terms, it should be spelled out and the abbreviation indicated in parentheses at first appearance in the text.*

*The CONSORT Statement is intended to improve the reporting of a randomized controlled trial (RCT), enabling readers to understand a trial's design, conduct, analysis and interpretation, and to assess the validity of its results. It emphasizes that this can only be achieved through complete transparency from authors.*

*Investigators and editors developed and revised the CONSORT (CONsolidated Standards of Reporting Trials) Statement to help authors improve reporting of two-parallel design RCTs by using a checklist and flow diagram. The most up-to-date revision of the CONSORT Statement is CONSORT 2010, which can be freely viewed and downloaded from this website. All previous versions of the CONSORT Statement are out-dated.*

*For further information please visit the CONSORT website.* <http://www.consort-statement.org/consort-2010>

***Note:*** *Please refer to the following link for the ICH E3 Guidance documents which contain detailed information and description of the ‘contents’:*

<http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html>

***Note:*** *The Sponsor can assist the trial team with the submission to the MHRA if necessary.*

*For more information on submission to the MHRA please refer to:*

<http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Safetyreporting-SUSARsandASRs/index.htm>

***Note:*** *The Sponsor delegates the REC submission of the End of Trial Report to the Chief Investigator and their team.*

*For information on submission to REC please refer to:*

<http://www.hra.nhs.uk/research-community/end-of-study-and-beyond/notifying-the-end-of-study/>

**THE END OF TRIAL REPORT SHOULD BE SUBMITTED TO THE CCTU FOR FINAL REVIEW PRIOR TO SUBMISSION TO ANY REGULATORY BODY/PUBLICATION AS PER CCTU/SOP004**

**END OF TRIAL REPORT**

|  |  |
| --- | --- |
| **Trial Identification and Report Information** | |
| **Title** |  |
| **Chief Investigator:** |  |
| **EudraCT no.:** |  |
| **REC Ref no.:** |  |
| **R&D no.:** |  |
| **Sponsor:** |  |
| **Sponsor’s Address:** |  |
| **Trial Statistician:** |  |
| **Final Data Analysis carried out by:** |  |
| **Author of the report:** |  |

**The content and layout in this flow chart can be adapted for different trial design, e.g. further allocation arms can be added if applicable.**

## Enrollment

Assessed for eligibility (n= )

Excluded (n= )

  Not meeting inclusion criteria (n= )

  Declined to participate (n= )

  Other reasons (n= )

Randomized (n= )

Allocated to intervention (n= )

 Received allocated intervention (n= )

 Did not receive allocated intervention (give reasons) (n= )

## Follow-Up

## Analysis

## Allocation

Analysed (n= )  
 Excluded from analysis (give reasons)

(n= )

Allocated to intervention (n= )

 Received allocated intervention (n= )

 Did not receive allocated intervention

(give reasons) (n= )

Lost to follow-up (give reasons) (n= )

Discontinued intervention (give reasons)

(n= )

Lost to follow-up (give reasons) (n= )

Discontinued intervention (give reasons) (n= )

Analysed (n= )  
 Excluded from analysis (give reasons) (n= )

|  |  |
| --- | --- |
| **Trial Summary** | |
| **Final Protocol version:** |  |
| **Study Design:** | *Include:*  *Trial type and phase*  *Medical condition or disease under investigation*  *Introduction, synopsis, study duration* |
| **No. of participants:** | *Include:*  *No. set out to recruit in protocol and no. recruited at end of trial*  *Methods of assigning participants to treatment group* |
| **Investigational Medicinal Products:** | *Include Name of IMP, dosage, formulation, MA no. if applicable. If IMP is based on active ingredients, please state as such.* |
| **Date of End of Trial:** | *Include date of completion of trial in all participating centres in all countries within the EU if applicable. Information on study early termination if applicable, including justification for early termination if applicable* |
| **Reported Serious Breaches:** | *List all serious breaches reported for this trial, actions taken to mitigate them and if these have impacted on trial data and how.* |
| **Significant deviations identified during the trial:** | *List all categories of significant deviations detected/reported during the trial, actions taken to mitigate them and* |

|  |  |
| --- | --- |
| **Statistical Analysis and Main Findings** | |
| **Trial objectives and endpoints:** | *Include primary and secondary objectives and end points of the trial as defined in the current protocol at time of the report.*  *Have the trial objectives and end points changed during the trial, if they have, please list the changes, reason for the change and what effects the changes have on the data.* |
| **Trial Analysis Population:** | *Indicate proportion of enrolled participants of which evaluable as per the current protocol at time of the report, taking into account of the following and how they were handled statistically:*  *Treatment compliance*  *Protocol compliance*  *Removal of patients from therapy or assessment*  *Has the trial analysis population changed during the trial, for example change in eligibility criteria, if it has, please lists the changes, reason for the change and what effects the changes have on the data.* |
| **Statistical Methods:** | *Include Statistical Analysis carried out and if this was as defined in the protocol and the IRAS form.*  *Has the trial statistical methods changed during the trial, if it has, please list the changes, reason for the change and what effects the changes have on the data.* |
| **Results:** | *Include findings from the trial with supporting statistics* |
| **Conclusion:** | *Conclude findings and if trial objectives of were met stating further research recommendation if appropriate* |

|  |  |
| --- | --- |
| **Dissemination of Research Findings and Publications** | |
| **To participants:** | *Include plan of dissemination of research findings, including feedback to participants, this should be consistent with plan for dissemination as stated in the protocol and REC application. Template letters to participants can be send to REC for their information with this report* |
| **Publications:** | *Include publications already submitted and those in planning, including name of journal, author, date of publication or planned submission whichever is appropriate.* |

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| **Chief Investigator’s Signature** | |
|  | Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |