MRC Clinical Trials Unit

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TRIAL REPORTING AND COMMUNICATION

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TRIAL REPORTING AND COMMUNICATION

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The following symbols may be used in this SOP:

Indicates a link to a related document

Indicates instructions to document trial-specific processes elsewhere

Throughout this document the MRC Clinical Trials Unit at UCL, will either be referred to as ‘MRC CTU at UCL’ or ‘the unit’. In instances where neither read well in the sentence, ‘the CTU’ may be used.

1 PURPOSE

The purpose of this SOP is to describe the different reports and other communications that may be produced with the aim of disseminating information about a particular trial or study, primarily to anyone outside the MRC CTU at UCL but also with reference to within-CTU communications. It applies to all MRC and UCL sponsored and/or MRC CTU-managed clinical trials and observational studies and should be applied as far as possible to all non-CTU-led studies.

This SOP should be read in conjunction with the 'Safety Reporting' and 'Trial and Comparison Closure – Reporting Requirements' SOPs.

2 RESPONSIBILITY AND ROLES

The following table lists the roles relevant to this SOP and a brief description of their responsibilities.

This SOP will be circulated for Read and Understood to all appropriate roles identified in the training matrix.

ROLE	RESPONSIBILITIES
Trial Management Group (TMG) / Trial Management Team (TMT)	• Assignment of responsibilities for each report • Checking content of reports (excluding closed reports to the Independent Data Monitoring Committee [IDMC]) • Providing information on relevant external developments for IDMC and TSC meetings • Dissemination of trial results
Trial Manager	• Coordinating and writing reports to TMG, Trial Steering Committee (TSC), funders and ethics and regulatory bodies
Clinical Project Manager (CPM)	• Assist with reports to TMG, TSC, funders and ethics and regulatory bodies if necessary, ensuring that reporting timelines are met
Trial Statistician	• Writing and checking open and closed IDMC reports. Contributing to the writing of sections of TMG and TSC reports, where access to trial data is required • Writing and checking all analysis reports • Checking content of trial communications to disseminate results • Uploading results of analysis to EudraCT, where applicable
Project Lead	• Review reports (excluding closed reports to the IDMC) • Dissemination of trial results
Programme Lead	• Review of some reports • Dissemination of trial results
Chief Investigator (CI), as referred to later	• Review reports (excluding closed reports to the IDMC) • Dissemination of trial results

3 PROCEDURES

3.1 GENERAL PRINCIPLES

MRC CTU encourages openness and the sharing of the nature and results of our research with the widest possible audience. All external reports and communications reflect back on the MRC CTU and must therefore be produced to the highest possible professional standards (liaise with the Communications Officer or Policy, Communications & Research Impact Coordinator within the MRC CTU for advice and information for support). In particular:

- Patient confidentiality must be maintained at all times as must confidentiality concerning interim results and some aspects of trial progress. All IDMC reports must be destroyed or stored securely after every meeting.
- Information for non-specialists and the public, including patients and carers, should be written in clear, non-scientific English, and translated and possibly backtranslated as appropriate.
- All formal reports should be dated and clearly labelled with the trial ID (and trial name, if applicable), the unique trial identifers (e.g. ISRCTN, NCT) and the full title. When compiling reports or communications involving trial data, the date the data were frozen for analysis should also be clearly stated.
- The MRC CTU, sponsors, TSC, IDMC, funders, investigators, laboratories, subgroups and participants should be acknowledged, as appropriate, in all written publications and in other reports or communications. Disclaimers should be added where necessary and according to any pre-specified text required by funders or agreed with other stakeholders.
- The MRC CTU and UCL logos should be used on all reports, letters and presentations pertaining to all trials with MRC CTU involvement. Other logos should be used as as agreed with collaborators and funders (please consult the contracts department if these are specified in the contracts).
- For journal publications and conference proceedings, it is very important that the requirements for open access publication are met: https://www.ucl.ac.uk/library/research-support/open-access. Publications must acknowledge the relevant Quinquennial Review (QQR) core funding grant code.

3.2 REGULATORY AUTHORITIES (FOR ALL CTIMPS)

The following describes the reports required by the UK Competent Authority (Medicines and Healthcare products Regulatory Agency, MHRA). Requirements may vary for other authorities in other countries but guidelines will be followed for each of the countries in which the trial is being run. For more detailed guidance on safety- and serious protocol breach-related reporting, refer to the ‘Safety Reporting’, ‘Serious Breach, Research Fraud or Financial Irregularity’ and ‘Urgent Safety Measures’ SOPs.

3.2.1 SAFETY REPORTS

For details of content and timing of safety reports, please refer to the ‘Safety Reporting’ SOP.

3.2.2 NOTIFYING URGENT SAFETY MEASURES

Urgent safety measures should be discussed within 1 working day with a medical assessor at the MHRA, and reported to the MHRA in writing within 3 days of implementation, followed by a Substantial Amendment Form.

For further details of this process, including additional notification requirements, see the 'Urgent Safety Measures' Working Instruction and SOP.

3.2.3 NOTIFYING SERIOUS PROTOCOL BREACHES

If, after discussion with the MRC CTU Research Governance Committee, a Serious Protocol Breach is suspected, the MHRA should be informed.

For further details of timelines and processes, see the 'Serious Breach, Research Fraud or Financial Irregularity' SOP.

3.2.4 REPORTING THE TEMPORARY HALT OF A TRIAL

If the trial is halted for any reason, the sponsor should notify all concerned competent authorities and ethics committees.

For further details see the 'Trial and Comparison Closure – Reporting Requirements' SOP.

3.2.5 REPORTING THE END OF A TRIAL

The "end of trial" should be defined in the protocol. Regulatory requirements for End of Trial reporting relate to this date, rather than the date when the trial was closed to recruitment, if these are different.

The reports required are outlined in the 'Trial and Comparison Closure – Reporting Requirements' SOP.

3.3 RESEARCH ETHICS COMMITTEES (RECS)

This section relates predominantly to UK-based trials and the Health Research Authority (HRA) website (https://www.hra.nhs.uk/) can be accessed for further relevant information. For studies based outside the UK, the trial teams must check the reporting requirements of their relevant ethics committees. For more detailed guidance on safety- and serious protocol breach-related reporting, refer to the 'Safety Reporting', 'Serious Breach, Research Fraud or Financial Irregularity' and 'Urgent Safety Measures' SOPs.

3.3.1 SAFETY REPORTS

The content and timing of safety reports (particularly Serious Breaches and Urgent Safety measures) to RECs are provided in the 'Safety Reporting', 'Serious Breach, Research Fraud or Financial Integrity' and 'Urgent Safety Measures' SOPs.

3.3.2 ANNUAL PROGRESS REPORT (ALL TRIALS)

Annual progress reports should be submitted to the main REC which approved the trial on the first anniversary of the favourable opinion being granted and annually (within 30 days) thereafter until the end of the trial. Following receipt of the first progress report, the chair of the main REC has the discretion to waive the requirement for further reports on receipt of a written request from the chief investigator. This might be appropriate where a study has completed recruitment and intervention, but has a long period of follow-up with minimal involvement of participants.

3.3.3 REPORTING THE END OF A TRIAL

The "end of trial" should be defined in the protocol. Ethics requirements for End of Trial reporting relate to this date, rather than the date when the trial was closed to recruitment, if these are different.

The reports required are outlined in the 'Trial Closure – Reporting Requirements' SOP.

3.4 TRIAL STEERING COMMITTEE (TSC)

The Trial Manager and Trial Statistician has responsibility for putting together the TSC report, with input from other members of the trial team or TMG as required. This report will typically contain data on accrual, centre accreditation status and data quality, and a report from the last meeting of the IDMC. The template TSC report may be used, but this is not mandatory. The TSC should be provided with information about other relevant external data; this may be provided by the TMG through the MRC CTU or the Chief Investigator. On an ad-hoc basis, the TSC may also need to approve, or be informed of, protocol amendments, details of presentations and publications and external requests for data. Refer to the trial-specific TSC charter for details of additional reporting and review requirements.

Templates for parts A, B and C of the TSC report can be found on SOPbox.

3.5 INDEPENDENT DATA MONITORING COMMITTEE (IDMC)

The IDMC report would usually contain data on accrual, form compliance/data quality, baseline, follow-up, endpoint and/or safety data (and other data as requested by the IDMC), and is the only report produced during the trial that may include outcome presented by randomised group. Presentation of data by randomised group should be considered and only undertaken if there is reason to do so. A clear distinction needs to be made between what is included in the open and closed parts of the report.

The structure and content of the IDMC report is described in the 'Guidance Document for Statistical Analysis Plans (SAP) for IDMC Reports and Final Analyses' working instruction.

The Trial Statistician is responsible for producing and presenting the IDMC report to the IDMC. The report should be kept confidential, given to the IDMC members in a confidential fashion (e.g. if emailed should be password protected), and must be destroyed at the end of the IDMC meeting or stored securely.

As for the TSC, the IDMC should be provided with a summary or detailed information about other relevant external data; this may be provided by the TMG through the MRC CTU or the CI.

3.6 TRIAL MANAGEMENT GROUP (TMG)

The Trial Manager and Trial Statistician is responsible for putting together reports covering accrual, form compliance/data quality, patient characteristics, loss to follow up and other operational issues or concerns as required. The frequency of meetings will vary but is typically monthly; in the early stages of the trial, meetings could be as often as weekly. The content of the report may depend on the frequency of the meetings. There is no standard MRC CTU format for TMG reports but it is suggested that the non-confidential sections of the IDMC report should generally be used as a basis.

3.7 FUNDERS

The funding bodies will typically require regular updates on trial progress and publications and may require financial reports. Where funder-specific report forms are required (e.g. in the signed contract) these should be used; otherwise it is recommended that the TSC report format is used.

Funding bodies, particularly charities, may routinely produce press releases to coincide with trial launch and or publication, and should therefore be included in such discussions.

3.8 CLINICAL TRIALS REGISTERS

All MRC CTU clinical trials must be registered on at least one appropriate clinical trials register. These include ISRCTN, EUDRACT, ClinicalTrials.gov and the WHO International Clinicial Trials Registry Portal. ISRCTN is the preferred place to register a trial, but other registers can be considered if there is a need. (See the 'Trial Management' SOP for more information.)

Updates should be made to the register, where appropriate, to reflect developments such as accrual, closure to recruitment, trial closure and the publication of results.

3.9 PARTICIPATING SITES

3.9.1 LAUNCH MEETING

The TMG should decide whether a trial launch meeting is required. A launch meeting may be a good way of informing all the interested parties (investigators, patients groups, health professionals, and other interested agencies), about the forthcoming study start.

3.9.2 NEWSLETTERS

Newsletters can be sent out digitally and/or post and posted on the MRC CTU and/or trial-specific website if available. Newsletters aim to promote the trial and keep trial personnel or participants up to date with the progress of the trial. An email circulation list or address list should include not only participating health professionals, but also members of the TSC, IDMC, patient groups, funders and the sponsor, although not all these groups have to be sent newsletters if it is not deemed necessary.

3.9.3 INVESTIGATORS' MEETINGS

Investigators' meetings are recommended during the trial as a means of keeping representatives from participating sites updated about key trial activities and milestones, and to discuss ongoing trial issues.

3.9.4 TRIAL RESULTS PRIOR TO PUBLIC DISSEMINATION

Where feasible, all clinicians and research staff involved in the trial at participating sites should be given the opportunity to see the results of a trial prior to any public presentation, typically through a closed investigators' meeting.

3.10 PATIENT/TRIAL PARTICIPANTS

A brief summary of the main trial results and their interpretation, written in non-technical language (liaise with the MRC CTU Patient and Public Involvement Group to obtain the input of appropriate patient support groups), should be distributed to all investigators for them to pass on to participants once the relevant ethics approvals have been obtained. This is typically done at the end of the trial but in rare circumstances it can occur during the course of the trial. The investigators should provide this communication to interested trial participants. Discuss with the TMG/TSC and potentially refer to your REC if you feel there are any particular issues in relaying results back to patients directly. Examples of good lay summaries are available within the Unit; please contact the Patient and Public Involvement Group for advice and any templates/good examples. General guidance on informing participants of the results of research is provided on the HRA website:

https://www.hra.nhs.uk/planning-and-improving-research/best-practice/publication-and-dissemination-research-findings/

3.11 GENERAL PUBLIC

The MRC CTU should take every appropriate opportunity to report back to the general population on the work we undertake and the results of that work. The main ways in which this can be achieved are:

- Press Releases - The Project Lead should liaise with the MRC CTU Policy, Communications & Research Impact Coordinator who will liaise with the MRC and UCL Press Offices as appropriate.
- MRC CTU website – the MRC CTU Web Committee should be contacted for advice.
- Social media – the unit Twitter team can help with this.

3.12 WITHIN-CTU COMMUNICATIONS

All MRC CTU staff should have the opportunity to learn about new trials, major trial-specific issues or milestones in trials in a timely fashion. This can be done through the intranet, MRC CTU Weekly News emails (email to mrcctu.weeklynews@ucl.ac.uk), through presentations at Monday Lunchtime Seminars (contact the Seminar Committee: ictm.seminars@ucl.ac.uk) and/or General/disease theme Staff Meetings (contact the relevant administrative member of staff).

3.13 REPORTING THE RESULTS OF MRC CTU TRIALS

It is important that trial results are disseminated to those involved in the trial and the wider scientific community in a timely manner. The process for this should begin in good time and take into account any requirement for creating localised communications materials for trials that operate internationally. The Unit Communications Strategy (available on the MRC CTU intranet) sets out a minimum standard package of tools that all our clinical studies should use to communicate their results: scientific presentation; peer-reviewed journal article; results summary/letter for participants; news story for the MRC CTU website; tweet(s). Major trial results should also be communicated through other tools and channels in addition, as identified in the trial's research impact strategy. (See the 'Strategies for Maximising and Measuring the Impact of MRC CTU at UCL Research' Working Instruction).

All trials must be published in the best quality and most high profile journal that is possible. Ideally, authorship should be agreed before the trial commences and written into the protocol but is decided by the TMG with input from the TSC in case of dispute. If journals allow, Group Authorship should be considered for reports of large international trials involving several trials groups e.g. on behalf of the Trial Management Group. If individual authors are named, consideration should be given to including the Chief Investigator(s), Statistician(s), Project Leader, Trial and Data Manager(s), as well as (if appropriate) key investigators (major contributors), relevant expert advisors e.g. health economists, but not the IDMC nor independent members of the TSC.

When deciding on who should be included as an author it is recommended to refer to the International Committee of Medical Journal Editors (ICMJE) guidance which states that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND

- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

In addition to any named authors, the main trial publication should also acknowledge the patients who participated in the study, all relevant expert advisors, and key staff at local centres, as well as the TSC, IDMC, funders, and collaborating patient groups and pharmaceutical companies. The level of investigator involvement may also be indicated e.g. those entering more than x patients or 10% of the total intake.

It is important to honor any contractual obligations on who reviews the final publication, e.g. Funders, industry collaborators, TSC and IDMC etc.

All publications involving MRC CTU staff should be logged using the publications form available from the intranet.

For journal publications and conference proceedings, it is very important that the requirements for open access publication are fulfulled as early as possible and are in place at the time of manuscript acceptance. Publications that are not deposited into UCL Discovery within 3 months of the date of first online publication cannot be considered for the Research Excellence Framework (REF). Please consult the UCL open access webpages for details:https://www.ucl.ac.uk/library/research-support/open-access.

Publications must acknowledge the relevant Quinquennial Review (QQR) core funding grant code. Please ensure that any relevant parties are made aware of journal embargoes that are in place.

4 APPENDIX: SUMMARY OF COMMUNICATION AND REPORTING SOP

4.1 PRE-RECRUITMENT/TRIAL LAUNCH STAGE

Essential

- Update MRC CTU website study page
- Inform Twitter team or other social media contacts
- Submit trial information for Clinical Trial Registration (see 'Trial Management' SOP for more information)

Optional

- Launch meeting
- Newsletters
- Editorials or articles for relevant journals and/or stakeholder groups.
- Inform MRC CTU Weekly News
- Consider introductory presentation at Monday seminar or General Staff Meeting
- Promotion at relevant conferences by presentations or posters

4.2 DURING TRIAL ACCRUAL/FOLLOW-UP

Essential (for UK-based trials - those operating in other countries should follow requirements for reporting to the local Competent Authority / Research Ethics Committee)

- Safety reports and urgent safety measures to main REC and MHRA (for CTIMPS)
- Discuss suspected Serious Protocol/GCP Breaches with the Research Governance Committee immediately; if confirmed, report to MHRA and main REC
- Annual Progress report to main REC
- Reports to Funders, IDMC, TSC, TMG
- Report temporary halt of trial to MHRA and main REC
- Update trial registration website(s) as necessary
- Update MRC CTU website study page

Optional

- Newsletters
- Inform Twitter team or other social media contacts
- Abstracts and/or publications relating to study design, baseline data or sub-studies/sub-analyses may also be considered during the trial
- Promotion at relevant conferences by presentations or posters
- Investigators' meetings are recommended during the trial to discuss ongoing trial issues

4.3 END OF RECRUITMENT

Essential (for UK-based trials - those operating in other countries should follow requirements for reporting to the local Competent Authority / Research Ethics Committee)

- Notify MHRA and main REC if recruitment is prematurely stopped
- Notify sites of date last randomisations/registrations will be accepted
- Change MRC CTU website study page
- Inform Funders, TSC and IDMC
- Update Trial Registration website(s)

Optional

- Inform MRC CTU Weekly News when accrual is complete
- Inform Twitter team or other social media contacts

4.4 CLOSE OF STUDY

Essential (for UK-based trials - those operating in other countries should follow requirements for reporting to the local Competent Authority / Research Ethics Committee)

- Send declaration of End of Trial Notification to MHRA and main REC (all trials)
- For CTIMPs, upload results to EudraCT where required (i.e. if study has a EudraCT number; see 'Uploading Trial Results to EudraCT' Working Instruction) and send End of Trial report (usually the primary publication) to main REC (all trials) within 12 months of the end of trial. The need to publish the main trial results before this 12 month deadline should be highlighted to any potential authors for the main trial publication.
- Change MRC CTU website study page
- Update Trial Registration website(s)

Optional

- A newsletter may be useful for informing all interested parties of trial closure

See Trial Closure and Reporting Requirements SOP for full details.

4.5 RELEASE OF RESULTS

Essential

- Publication of the main results in a peer-reviewed journal
- Contact the Policy, Communications & Research Impact Coordinator
- If feasible, the results should be discussed at a Closed participants meeting
- Lay summary to be sent to sites to discuss with patients
- Update Trial Registration website(s)
- Update MRC CTU website study page
- Add a news story for the MRC CTU website

Optional

- Press release
- Inform Twitter team and other social media contacts

- Notify MRC CTU Weekly News of any upcoming presentations/publications/press releases
- Present results at Monday Lunchtime Seminar/General Staff or Theme Meetings