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Imperial College Healthcare NHS Trust

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End of Study Procedure

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Version	Date	Reason for Change
Version 1.0	30 May 2007	Annual review
Version 2.0	20 Jun 2008	Annual review
Version 3.0	08 Feb 2010	Formation of Joint Research Office
Version 4.0	14 Jul 2011	Annual review
Version 5.0	03 Dec 2012	Annual Review
Version 6.0	18 Feb 2015	Scheduled Review
Version 7.0	25 Oct 2017	Annual Review
Version 8.0	29 May 2018	Update of procedure for clinical trials & end of study
Version 9.0	19 Oct 2020	Scheduled Review Templates removed & administrative changes. JRCO name change to RGIT.
Version 10.0	07 Jan 2021	Updated regarding updates to EoS submission for CTIMP studies after Brexit Amendments due to leaving the European Union from 1st January 2021
Version 11.0	25 Mar 2021	Update in line with HRA guidance
Version 12.0	24 Sep 2021	Updated in line with HRA final reporting changes
Version 13.0	02 Nov 2021	Updated for studies using CWOW IRAS
Version 14.0	14 Dec 2023	Scheduled Review
Version 15.0	27 Apr 2026	Updates following legislative changes

Table of Contents

1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure for notifying the relevant bodies about the end of a study for clinical trials of an investigational medicinal product (CTIMPs) as well as all other non-CTIMP clinical research. The procedure for submitting the final research reports is also described.

2. INTRODUCTION

The Medicines for Human Use (Clinical Trials) Regulations 2004 ("the Clinical Trials Regulations"), as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 and the Health Research Authority (HRA) state that for all clinical trials of Investigational Medicinal Products (CTIMPs), and for all other clinical research (non-CTIMPs), written notification of the end of study should be submitted within 90 days of the end of project. If the Chief Investigator (CI) requires a study extension, for example because fewer than expected patients were recruited, this extension request should be notified as a minor modification to the study.

The definition of the conclusion of the research should be provided in the protocol. In most cases, it will be the date of the last visit of the last participant or the completion of any follow-up monitoring and data collection as described in the protocol. Any change to this definition should be notified as a modification (please see RGIT_SOP_006 on the SOP, Associated Documents & Templates page).

The conclusion of the research study **does not** mean the completion of data analysis or publication of results. However, HRA guidance now states for studies involving human tissues, the analysis of samples should be undertaken as part of data collection before the end of study is declared. Final analysis of the data (following 'lock' of the study database) and report writing is normally considered to occur after formal declaration of the end of the project.

Before the end of study, the CI should review the plans that have been approved by the REC for use of tissue and data collected during the course of the study, providing information to participants (a legal requirement for CTIMPs) and publication of results (a legal requirement for CTIMPs). If there is a need to make any changes to these approved arrangements, it should be considered whether a substantial modification is required before submitting the end of study notification.

2.1. End of study under HRA Approval

Where a project has HRA Approval and has been reviewed by a REC, you need only inform the REC when your study has ended. Where a project has HRA Approval and was not reviewed by an NHS REC, you will need to tell HRA when the project has ended. You should send this notification by email to HRA approvals (Cited 10 Mar 2023) including your IRAS ID and your contact information (phone and email).

2.2. Declaration of end of a clinical investigation of medical device to MHRA

Manufacturers are required to notify the MHRA when a clinical investigation comes to an end.

2.3. Notification of end of study to Confidentiality Advisory Group

If you have an application with the Confidentiality Advisory Group, when your study is completed, you should notify the **Confidentiality Advice Team** as soon as possible in writing. Once received, the Confidentiality Advice Team will review the information provided, update the approval register, and write to confirm receipt of the application closure notice.

The application will remain on the approval register on the HRA website for at least 12 months following notification of application closure.

3. PROCEDURE FOR NOTIFICATION OF END OF STUDY FOR CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS (CTIMPs)

3.1. Lines and method of communication

It is the responsibility of the Chief Investigator (CI), or someone delegated by the CI, to notify the end of the trial by completing the Notification of End of a Clinical Trial Medicine (Appendix 1: RGIT_TEMP_041).

This should first be emailed to the Sponsor for review prior to submission. For Imperial College Academic Health Science Centre (AHSC) studies, this is the RGIT CTIMP team.

For clinical trials which were approved through CWOW:
i) The end of trial declaration should be completed and submitted through IRAS. This automatically submits the notification to the REC and MHRA. Guidance on using IRAS to submit an end of trial declaration form can be found in the Step-by-step guide to using IRAS for combined review (Step by step guide to using IRAS for combined review - Health Research Authority

For clinical trials not approved through CWOW:
i) The end of trial declaration form (Clinical trials for medicines: manage your authorisation, report safety issues - GOV.UK) should be sent separately to the licensing authority (MHRA) and the ethics committee (REC). The form should be submitted via MHRA Submissions (MHRA Portal) and emailed to the ethics committee which gave initial favourable opinion for the trial. Please contact the RGIT monitor for MHRA submissions account registration.

After submission, an acknowledgement will be issued by email (and through IRAS for combined review trials).

The end of trial form should only be submitted when the trial has ended in all countries. However, the MHRA may be informed by letter/e-mail when the trial finishes in the UK which will signal the suspension of the annual service fee for maintaining the Clinical Trial Authorisation. No acknowledgement will be issued if the submission was related to the local end of trial. Please note that once the global end of trial notification has been received by the authorities, it is not possible to submit any further clinical documents other than a summary of results.

For multi-national trials, the CI (or someone delegated by the CI) must notify the competent authorities of all member states concerned, as well as the Ethics Committees for each country, that the clinical trial has ended. For studies running in the EU, submission should be via Common European Submission Portal (CESP).

3.2. Timing of notification

LOCATION OF TRIAL	WHEN TO NOTIFY END OF STUDY
Trial is running **only** in the UK	When the trial ends
Trial is running **only** in countries outside the UK	When the trial ends
Trial is running in the UK **and** in other countries, trial ends in all countries *at the same time*	When the trial ends
Trial is running in the UK **and** in other countries, trial ends in UK *at a different time*	When trial ends in the UK **and** When trial ends in all other countries

The Chief Investigator, acting on behalf of the Sponsor, must notify the required organisations of the end of the trial ***within 90 days*** of the trial ending (as defined in the protocol).

3.2.1 Trial Early termination

If a trial is terminated early (prior to the date or event specified in the protocol), the CI must notify the REC, Sponsor, and MHRA within **15 days** as per the same routes described above. The CI must clearly explain the reasons for termination in their submission.

The end of trial declaration will be reviewed by the licensing authority and REC, and requests for additional information may be raised. Once the licensing authority has sufficient information, the sponsor will be informed that the end of trial declaration has been accepted.

Where it is necessary to seek ethical review of early termination related actions, such as informing subjects or arranging continuing care and follow-up outside the trial, a substantial modification would need to be submitted alongside the declaration of early termination.

If a trial terminates early and it has recruited participants in the UK, the sponsor is encouraged to provide some form of summary results to the participants. This should communicate the results that were obtained for the study and the rationale behind the study being terminated early.

3.2.2 Trial does not commence

Under regulation 26 of the Clinical Trials Regulations, a clinical trial approval will lapse two years from the date on which the trial was approved if no participants have been recruited (i.e. have signed the consent form) to take part in the UK trial.

The licensing authority will monitor the status of the trial's approval. If the approval lapses, the sponsor will be contacted via email to confirm this. The sponsor will then need to submit an end of trial notification.

If the CI decides not to commence a trial (or understand there are issues which may prevent the trial from commencing within the 2-year period), they should notify the REC, Sponsor and MHRA as soon as possible and clearly explain the reasons for not starting the trial. Sponsors can apply to the authorities for an extension of this period by emailing clintrialhelpline@mhra.gov.uk, explaining both why the extension is needed and the length of the proposed extension.

The authorities can grant an initial extension of up to 36 months beyond the lapse date and a further extension of up to 24 months, which must be requested (through the same process) before the previous extensions ends.

The authorities will respond to extension requests via email within 30 calendar days or, if the trial is awaiting approval, at the same time as the outcome of the application for clinical trial approval is issued.

Transitional arrangements for Lapse of Clinical Trial Approval

Old rules clinical trials
If an application to approve a clinical trial is submitted before 28 April 2026 and the trial does not start within the 2-year timeframe, the Medicines for Human Use (Clinical Trials) Regulations 2004 as in force immediately before 28 April 2026 are in effect (meaning that this does not apply)

New rules clinical trials
If an application to approve a clinical trial is submitted on or after 28 April 2026, the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 are in effect (as described in the section above).

Area	Old rules clinical trials (application for clinical trial approval submitted before 28 April 2026)	New rules clinical trials (application for clinical trial approval submitted on or after 28 April 2026)
Lapse of clinical trial approval after 2 years where no participants are recruited	The Medicines for Human Use (Clinical Trials) Regulations 2004 as in force immediately before 28 April 2026 (meaning that this does not apply)	The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

4. PROCEDURE FOR NOTIFICATION OF END OF STUDY FOR ALL OTHER CLINICAL RESEARCH (Non-CTIMPs)

4.1. Lines and method of communication

It is the responsibility of the Chief Investigator (CI), or someone delegated by the CI, to notify the end of the study to the following:

i) the REC which gave a favourable opinion of the research;
ii) the Health Regulatory Authority (Cited 10 Mar 2023) **only for studies exempt from REC approval**
iii) the Sponsor - for Imperial College Academic Health Science Centre (AHSC) studies, this is the RGIT.
iv) the Confidentiality Advisory Group (CAG) **(if applicable)**

The NRES declaration of the end of a study form (Appendix: 2-RGIT_TEMP_042) must be completed and sent by email.

If the study uses the Combined Ways of Working (CWOW) IRAS system, then the End of Trial can be submitted via the system by clicking on the Reporting button.

4.2. Timing of notification

LOCATION OF TRIAL	WHEN TO NOTIFY END OF STUDY
Trial is running **only** in the UK	When the trial ends
Trial is running **only** in countries outside the UK	When the trial ends
Trial is running in the UK **and** in other countries, trial ends in all countries *at the same time*	When the trial ends
Trial is running in the UK **and** in other countries, trial ends in UK *at a different time*	When trial ends in the UK **and** When trial ends in all other countries

The Chief Investigator, acting on behalf of the Sponsor, must notify the required organisations of the end of the study ***within 90 days*** of the study ending (as defined in the protocol).

4.2.1 Study suspended or early termination

If a study is terminated early, the CI must notify the REC and the Sponsor within 15 days and clearly explain the reasons for suspension or termination. For this purpose, use the Appendix 2 Declaration of the End of a Study – RGIT_TEMP_042.

4.2.2 Study does not commence

If the CI decides not to commence a study, they should notify the REC and the Sponsor as soon as possible and clearly explain the reasons for not starting the study.

If the research does not commence within 12 months of the favourable opinion being issued, the Chief Investigator should send a written explanation for the delay. A further written explanation should be sent after 24 months if the research has still not commenced.

5. FINAL REPORT ON THE RESEARCH

5.1. End of trial reporting requirements for CTIMPs

Once the end of trial declaration has been approved (for both trials which reached their end of trial point and those which terminated early), under regulation 25(2) there is now a legal requirement that the CI completes the following (please see "Transitional Guidance" below for when the new rules must be followed):

- A final research report is submitted within 12 months to the public registry the trial was originally registered to (per regulation 25(2)(a)) before recruitment commenced (If the sponsor registered a trial with more than 1 registry, they will need to publish a summary of the trial results in all those registries).
- There is a summary of the results available to the trial participants (per regulation 25(2)(b)). This should be in a suitable format and in a manner that's understandable to participants or those who may have provided consent on behalf of the participant or other relevant people (See detailed guidance from the HRA on the requirement to publish the results of a clinical trial (Research transparency requirements for clinical trials - Health Research Authority).

Details of where the results have been published should be provided to the sponsor (RGIT CTIMP), licensing authority (MHRA), ethics committee (REC) and HRA within 12 months of trial completion. Please inform the HRA via the following email address (study.registration@hra.nhs.uk). For studies using the CWOW IRAS system, the Final Report can be submitted to both REC and MHRA using the reporting button.

If a sponsor submits their summary of trial results to a public registry and the registry does not publish them within the required timeframe, the sponsor should notify the HRA by emailing: study.registration@hra.nhs.uk. The email should include confirmation that the sponsor has submitted their summary of results and evidence of this (for example an email confirming submission or a screenshot of the submission page).

At any point before the 12-month deadline, sponsors may apply to the HRA for a deferral or waiver to one or both requirements, explaining why this is needed. Phase I clinical trials may be eligible for an automatic deferral of up to 30 months from the conclusion of the trial, which may be further extended on request (Deferrals in Phase 1 trials - Health Research Authority). Please note, where a deferral to the requirement to publish the results is in place, the sponsor should still provide a summary of the trial results to the licensing authority within 12 months of trial completion (which will be kept confidential). This may be required as a condition of approving the deferral.

For additional information on the deferral process, please refer to the links: Deferrals - Health Research Authority & Deferrals in Phase 1 trials - Health Research Authority.

If the trial is sponsored by the holder of a UK marketing authorisation and involves the use of that authorised medicinal product use in a paediatric population, the results must be submitted to the licensing authority within the **6 months** beginning with the day on which the trial ended. The details of where the results have been published should still be submitted to the ethics committee within 12 months of trial completion.

Under regulation 17(2)(b) of the Clinical Trials Regulations, the licensing authority can take into account any outstanding failures to comply with regulation 25(2)(a) (unless a deferral or waiver has been approved by the ethics committee) when assessing future applications by the same sponsor.

Transitional arrangements for transparency regulations

Old rules clinical trials
If an application to approve a clinical trial is submitted before 28 April 2026 and the trial ends prior to 28 April 2026, the transparency requirements in the amended Clinical Trials Regulations do not apply.

If an application to approve a clinical trial is submitted before 28 April 2026 and the trial ends on or after 28 April 2026:

- A summary of the results of the clinical trial must be published in the same public registry that it was registered in.
- The requirement to provide an accessible summary of results for participants does not apply, although sponsors of old rules clinical trials are still encouraged to do so.

New rules clinical trials
If an application to approve a clinical trial is submitted on or after 28 April 2026, all transparency provisions in the amended Clinical Trials Regulations will apply as per the guidance at the top of this section.

Area	Old rules clinical trials (application for clinical trial approval submitted before 28 April 2026)	New rules clinical trials (application for clinical trial approval submitted on or after 28 April 2026)
Publishing the results of a clinical trial in a public registry	**If the trial ends before 28 April 2026:** The Medicines for Human Use (Clinical Trials) Regulations 2004 as in force immediately before 28 April 2026 **If the trial ends on or after 28 April 2026:** The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025	The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

Offering an accessible summary of results to participants	The Medicines for Human Use (Clinical Trials) Regulations 2004 as in force immediately before 28 April 2026 (meaning that this is not required)	The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

5.2. End of trial reporting requirements for non-CTIMPs

The Chief Investigator, acting on behalf of the Sponsor, must submit a final research report to the REC, HRA, and Sponsor. The final report, including final results, should be submitted within one year of the 'end of trial' for non-pediatric studies and within six months of the end of study for Marketing Authorisation Holder (MAH)-sponsored pediatric studies. This timeline may be extended in cases where a reasonable cause/factor/impediment may delay the final report submission including delays in obtaining final primary and secondary analyses and related results.

The report must be submitted as follows:

- **Sponsor**: Inform by email that the online Final Report has been submitted and the acknowledgment email received; for Imperial College Academic Health Science Centre (AHSC) studies, this is the RGIT.
- **REC &HRA:** Submit via the standardised form on the HRA website

If the study has been registered on a public database, the records must be maintained, and the results need to be reported within the required time frame regardless of the outcome of the trial and regardless of potential planned or pending publications. See RGIT_SOP_022 on the SOP, Associated Documents & Templates page.

6. REFERENCES

Medicines: clinical trials hub - GOV.UK

Clinical Trials Toolkit (Cited 10 Mar 2023)

IRAS Amendment guidance pages (Cited 14 Mar 2023)

NHS Health Research Authority progress reports (Cited 10 Mar 2023)

NHS Health Research Authority ending your project (Cited 10 Mar 2023)

Contacting HRA (Cited 10 Mar 2023)

Final Report-frequently asked questions (Cited 10 Mar 2023)

Research in human subjects other than clinical trials of investigational medicinal products (Cited 10 Mar 2023)

Medicines for Human Use (Clinical Trials) Regulations 2004 (SI: 1031),Schedule 3, Part 4 (Cited 10 Mar 2023)

MHRA. Managing your clinical trial authorisation: End of trial (Cited 10 Mar 2023)

EC Europa reporting final results (Cited 10 Mar 2023)

Common European Submission Portal (CESP) (Cited 10 Mar 2023)

Confidentiality Advisory Group (CAG) (Cited 14 Mar 2023)

RGIT website (Cited 10 Mar 2023)

RGIT Staff list (Cited 10 Mar 2023)

7. APPENDICES

The following Appendices list the following Templates associated to this SOP which can be found on the SOP, Associated Documents & Templates page:

Appendix 1: Notification End of Clinical Trial Medicine – RGIT_TEMP_041
Appendix 2: Declaration of the End of a Study – RGIT_TEMP_042