

Guidance for applicants using the deferral process: registration of UK CTIMPs in ISRCTN

Introduction

This guidance explains how to prospectively register a UK clinical trial of an investigational medicinal product (CTIMP) with ISRCTN when the Health Research Authority (HRA) has agreed a deferral of publication of full trial details in line with the UK clinical trials legislation¹. It replaces previous guidance based on the EU Clinical Trials Regulation. It applies to any CTIMP for which the HRA has approved a deferral. The purpose of this document is to describe the process and requirements only.

Overview of deferrals under the UK regulations

Under the 2025 reforms to UK clinical trial regulations¹, the HRA administers a [deferral mechanism](#) that allows sponsors to prospectively register trials with a minimal dataset and delay publication of full trial details in specific circumstances described on the HRA website. Deferrals are usually granted for an initial period of 30 months after the end of the trial. Sponsors must apply for an extension if they wish to continue the deferral beyond the initial period but, while extensions will allow sponsors to further delay publication of summary results, extensions will usually not apply to the registration element of the UK transparency requirements. Therefore, full details of the trial registration record must usually be provided to ISRCTN within 30 months after the end of the trial, and summary results must be published in ISRCTN by the deferral expiry date.

The HRA requires that registration must be completed and the minimal dataset published before the recruitment of the first participant, or within 90 days of trial approval, whichever is earlier. Deferral does not permit retrospective registration.

Purpose of ISRCTN registration when a deferral is in place

Registering a deferral-compliant minimal dataset in ISRCTN allows sponsors to meet legal requirements for prospective registration while withholding information that cannot yet be made public. Deferred fields must contain a standard deferral statement until the sponsor provides the full details by the deferral expiry date.

Process for prospectively registering a CTIMP with an HRA-approved deferral

1. Register for an ISRCTN account if you do not already have one

¹ The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (SI 2025 No. 538), updating The Medicines for Human Use (Clinical Trials) Regulations, 2004 (SI 2004 No. 1031).

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2. Enter trial details in the ISRCTN form and use deferral statements (see ISRCTN Dataset section) in place of information that will be supplied later
3. Submit the trial allowing time for editorial review before the first screening visit. Submission shortly after applying for MHRA and research ethics committee approval is recommended
4. When ISRCTN acknowledges receipt, reply by email. Quote your five-digit submission number and confirm that the HRA has agreed a deferral for your trial or that the trial is a phase I trial in healthy volunteers only that qualifies for automatic deferral. ISRCTN may request evidence of the HRA approval
5. Await editorial review and respond as necessary
6. Once the sponsor has approved the final minimal dataset, ISRCTN will publish the record and provide the ISRCTN number
7. Keep dates up to date when prompted. If the record is already up to date, there is no need to respond
8. After MHRA and research ethics committee review, provide the date of ethics approval to ISRCTN.
9. On or before the deferral expiry date, the full trial registration dataset needs to have been published, with information added to any fields which contained the deferral statement. You may update the public title if required. Guidance on filling out these details in full can be found [here](#).
10. Provide summary trial results to complete the WHO minimum dataset when available. ISRCTN can accept a file (recommended format: PDF or Word document) containing your results through either the 'Report your results' functionality or via email to info@isrctn.com. Please see the ISRCTN website for additional guidance on structuring results.
11. Later during the lifecycle of your trial, you may add links to publications or results and provide the generic name or other identifiers for the investigational product

If your trial was submitted for combined review by the MHRA and a research ethics committee **before 28th April 2026**, please see our [previous guidance for deferred full registration](#).

Important considerations

- It is not possible to publish a minimal dataset for part of a trial in ISRCTN and publish full details of other parts elsewhere
- If you register full details of the trial in any other research registry before the deferral expires, you must inform the HRA. The trial must then be fully registered in ISRCTN in line with HRA expectations
- Deferral does not alter the requirement for prospective registration. Studies registered with a minimal dataset after the first screening visit will be considered retrospectively registered and this is not permitted under the UK regulations

- The date of first enrolment in ISRCTN must reflect the first screening visit. If registration occurs after the anticipated date but before the actual date, ISRCTN may update the date of first enrolment if you provide evidence of the actual date of first screening
- **All entries in ISRCTN are permanent. Ensure that no commercially sensitive information is included in the initial dataset**

Eligibility for HRA deferral

For information on the types of CTIMPs eligible for an HRA deferral, see the HRA guidance: [HRA clinical trial regulations reform](#).

Under the new regulations, all Phase I trials in healthy volunteers only will receive an automatic deferral from the HRA.

ISRCTN dataset for a CTIMP with deferred publication

This table describes the information to be submitted to ISRCTN when registering a CTIMP with deferred publication. Deferred fields must include a deferral statement referring to publication of full details on or before the deferral expiry date. **All fields must be completed in accordance with ISRCTN requirements and updated to provide full details by the deferral expiry date.**

Deferral statements to use in deferred fields:

For phase I trials in healthy volunteers only: This is a phase I trial in healthy volunteers only and qualifies for an automatic deferral. The full details will be added to the trial record on or before the deferral expiry date

For trials other than phase I trials in healthy volunteers only that are submitted for registration before deferral is confirmed: The sponsor has requested a deferral. The full details will be added to the trial record on or before the deferral expiry date

For trials other than phase I trials in healthy volunteers only that are submitted for registration after deferral is confirmed: The Health Research Authority has approved a deferral. Full details will be added to the trial record on or before the deferral expiry date

Field	Initial registry entry for deferred trials	Guidance for applicants
Study overview		
Initial information		
Responsible registrant declaration	Tick box to confirm that you are an appropriate representative of the	

Field	Initial registry entry for deferred trials	Guidance for applicants
	trial's primary sponsor and that, as the responsible registrant, you understand your responsibilities	
Does this study include participants from UK centres?	Select Yes	Studies without UK trial locations are not eligible for publication of a minimal record through a deferral
Is this study interventional or observational?	Select option	Select Observational or Interventional. This appears as Study type in the public record
Title and additional identifiers		
Registration number and date	Allocated by registry. ISRCTN will add an internal marker indicating that full publication is deferred	
Public title	Deferred registration: [CRO/trial location name] code: XXX	Give a neutral public title and include a site code or other identifier. The full public title may be added on or before the deferral expiry date
Scientific title	Deferred registration: [CRO/site name] code: XXX [Full scientific title to be added on or before the deferral expiry date]	Provide the full scientific title on or before the deferral expiry date

Field	Initial registry entry for deferred trials	Guidance for applicants
Study acronym		If applicable, add on or before the deferral expiry date
Secondary identifying numbers	IRAS [IRAS project ID] [CRO/site code]	Provide the IRAS project ID and another suitable identifier. Include the sponsor protocol code if it can be published, otherwise provide it on or before the deferral expiry date . Do not use the deferral procedure if the trial is already public in another registry
Study dates		
Date of first enrolment	dd/mm/yyyy	Enter actual or planned date of first screening visit. If registration is before or on this date the trial is prospectively registered; otherwise it is retrospectively registered
Date of final enrolment	dd/mm/yyyy	Enter planned date of the first visit of the last participant. Provide the actual date on or before the deferral expiry date or update the anticipated date when prompted
Completion date	dd/mm/yyyy	Enter anticipated date of end of trial (typically date of last participant last visit). Provide the actual end date on or before the deferral expiry date or

Field	Initial registry entry for deferred trials	Guidance for applicants
		update the anticipated date when prompted
Study design		
Allocation	Select option	Select from: Randomized controlled trial, Non-randomized controlled trial, N/A single arm If any part of the trial is randomized, select Randomized controlled trial
Masking	Select option	Select from: Blinded, Open If any part of the trial is Blinded, select Blinded
Control	Select option	Select from: Placebo, Active, Historical, Dose comparison, None
Assignment	Select option	Select from: Single, Parallel, Crossover, Factorial, Sequential, Other. If Other is selected, a deferral statement may be used in place of details
Purpose	Select option(s)	Select from: Treatment, Prevention, Diagnostic, Supportive care, Screening, Health services research, Basic science, Device feasibility, Other
Eligibility criteria		

Field	Initial registry entry for deferred trials	Guidance for applicants
Health condition(s) or problem(s) studied	Healthy volunteers or Deferral statement	If non-therapeutic in patients, use a deferral statement and provide a brief descriptor on or before the deferral expiry date
Healthy volunteers allowed?	Select option	Select Yes or No
Key inclusion criteria	Healthy human volunteer or Deferral statement	For healthy volunteer studies you may enter healthy human volunteer. If patients or specific characteristics are required, provide a numbered list of inclusion criteria on or before the deferral expiry date
Lower age limit		Add on or before the deferral expiry date
Upper age limit		Add on or before the deferral expiry date
Sex	Select option	Select Both, Female only or Male only
Key exclusion criteria	Does not meet inclusion criteria or Deferral statement	If patients or specific characteristics are required, provide a numbered list of exclusion criteria on or before the deferral expiry date
Target sample size at registration	[Number of planned participants]	Enter the planned number of participants
Final enrolment number		Update with total number of enrolled participants on

Field	Initial registry entry for deferred trials	Guidance for applicants
		or before the deferral expiry date
Study description		
Study objectives	Deferral statement	Provide details on or before the deferral expiry date
Interventions or methodology	Deferral statement	Provide details of treatments, randomization, route and duration on or before the deferral expiry date
Intervention type	Select option	Select: Not specified, Drug, Supplement, Device, Biological or vaccine, Procedure or surgery, Behavioural, Genetic, Other, Mixed
Phase	Select option	Select: Not specified, Phase I, Phase II, Phase III, Phase IV, Phase I/II, Phase II/III, Phase III/IV, Not applicable
Drug/device/biological/vaccine name(s)	Deferral statement	Provide details on or before the deferral expiry date
Primary outcome(s)	Deferral statement	Provide details on or before the deferral expiry date
Key secondary outcomes	Deferral statement	Provide details on or before the deferral expiry date
Information for participants		

Field	Initial registry entry for deferred trials	Guidance for applicants
Plain English summary of protocol	Deferral statement	Provide a lay summary on or before the deferral expiry date.
Countries of recruitment	Select option	Select countries from the search list
UK study participating centres		Create a trial location for each UK site
Study participating centre outside UK		Optional. If relevant, create a trial location for each site outside the UK
Contacts, sponsor, funder, ethics		
Contact for public queries Contact for scientific queries Principal investigator	[Contact name] [ORCID if available] [Professional address] [Telephone] [Email]	Enter three contacts. The principal investigator must be named. Scientific and public contacts may be a role or department. The principal investigator can serve as each of the three contacts
Sponsor	[Name of primary sponsor organisation]	Enter the name of the primary sponsor
Secondary sponsor	[Name of secondary sponsor organisation] or leave blank	Optional. If there is a secondary sponsor, click on 'Add' and then enter details.
Funder organisation	[Funder organisation]	Enter the funder name(s) or source(s) of support
Ethics approval required	Select option	Select Ethics approval required or Ethics approval not required

Field	Initial registry entry for deferred trials	Guidance for applicants
Ethics approval status	Select option	Select Not yet submitted, Submitted or Approved
Ethics committee approval – status date	dd/mm/yyyy	If not yet approved, provide the date of submission to the MHRA and research ethics committee. When available provide the date of approval, ideally before the trial starts
Ethics committee approval – ethics committee name	[REC name]	Provide the name of the research ethics committee
Ethics committee approval – address	[REC street address]	Provide the research ethics committee address
Ethics committee approval – city	[REC city]	Provide the research ethics committee city
Ethics committee approval – country	[REC country]	Select United Kingdom for UK research ethics committees
Ethics committee approval – postcode	[REC postcode]	Provide the research ethics committee postcode
Ethics committee approval – telephone	[REC telephone]	Provide the research ethics committee telephone number if available
Ethics committee approval – email address	[REC email address]	Provide the research ethics committee email address
Ethics committee approval – reference number	Ref: [REC reference number]	

Field	Initial registry entry for deferred trials	Guidance for applicants
Uploads and outputs		
Third party confirmation	Upload a file at submission or indicate that third party confirmation will be sent later	Upload evidence such as the trial application validation letter or an IRAS screenshot including the IRAS project ID. ISRCTN will record receipt but will not display the document
Do you plan to share individual participant data?	Select option	Select Yes or No
Individual participant data sharing plan	[Provide plan]	If Yes, provide a plan for de-identified participant data or indicate that the plan will follow later
Do you wish to upload anything else?	[Provide files intended for upload]	Optional uploads could include the participant information sheet or the publication and dissemination plan
Payment method	Funded registration	Select the applicable payment method

Notes on colour coding in this appendix: deferred field placeholders and references to the deferral expiry date are shown in **purple**.