Guidance for applicants using the deferral process: registration of UK Phase I clinical trials in ISRCTN: balancing transparency with commercial confidentiality

The EU Clinical Trials Regulation (EU CTR; Regulation EU No. 536/2014), which was implemented on 31 January 2022, introduced new transparency requirements for clinical trial data included in applications to EU Competent Authorities (CA). Registering UK Phase I trials in ISRCTN allows sponsors to meet those transparency requirements but protect commercially confidential information through deferral of publication of trial details.

Article 25 of the EU CTR requires that data submitted to an EU CA as part of an application dossier for clinical trial authorisation (CTA) or a substantial modification, made under the EU CTR, come from a clinical trial that meets minimum transparency requirements. Trials starting after the implementation of the EU CTR on 31 January 2022 must have been registered, *before the trial started,* in a public register that is a primary or partner registry of, or a data provider to, the WHO ICTRP. For trials that started *before* the implementation of the EU CTR, Article 25 can be satisfied through publication or retrospective registration, as described in the section *Guidance on retrospective registration of Category 1 trials that started before implementation of the EU CTR* (below).

The Article 25 transparency requirements do **not** apply to data in UK applications submitted to the MHRA/research ethics committee (REC). While it is a condition of UK ethical approval that trials be registered on a public registry, the Health Research Authority (HRA) allows sponsors to request a *deferral* of registration to protect commercially confidential information (or for other reasons where a strong justification is provided). Sponsors of trials with a deferral agreed by the HRA may satisfy Article 25 by registering limited information in ISRCTN as described below. Although it is not a UK requirement that sponsors register deferred trials before the deferral expires, the HRA has an expectation that sponsors will follow best practice and register deferred trials in ISRCTN as described below, even if the sponsor does not intend to submit the data as part of an application made to an EU CA under the CTR.

The instructions below allow prospective registration of UK Phase I trials in adults, in a WHO primary registry, in line with EU transparency requirements under the EU CTR, but protect commercially confidential information.

In 2015, the EU published transparency rules for clinical trials (*Appendix, on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited – EMA/42176/2014", EMA/228383/2015 dated 2 October 2015)*. Revised rules were adopted in October 2023 (*Revised CTIS Transparency Rules, EMA/263067/2023 dated 05 October*

2023). According to the rules, Phase I trials fall into Category 1 (pharmaceutical development clinical trials; see Appendix A). In recognition of the high commercial sensitivity of these non-therapeutic clinical trials and the negligible benefit to the public of publication of details of those trials, the rules specify that Category 1 trials will be registered prospectively but *publication* of all but limited trial details will be deferred. Publication of full trial details and trial results will be at 30 months after the end of the trial.

Like the EU register, ISRCTN is a primary registry of the WHO ICTRP and allows deferral of publication of certain details of clinical trials meeting the criteria for Category 1 trials as defined in the EU transparency rules. The data fields to be published in ISRCTN at the time of registration mirror those published in the EU register at the time of the decision on the trial, and the maximum deferral period matches that in the EU transparency rules. In line with those EU rules, registrants must submit for publication the remainder of the trial details within 30 months after the end of the clinical trial. To complete the WHO minimum trial registration dataset, registrants should also post summary trial results, ideally within 30 months after the end of the trial. Summary results can be posted in ISRCTN by uploading a file in the WHO format or providing a link to summary results on another registry, company website or repository. The following guidance explains how to register a Category 1 trial in ISRCTN but defer publication of all but limited details.

The sponsor, or an authorised sponsor's delegate (eg contract research organisation), can register the trial in ISRCTN. It is the responsibility of sponsors' delegates to ensure, before submission to ISRCTN, that they have the sponsor's written approval of the data to be entered in the register; please note that all entries in the register are **permanent** and cannot be deleted. If the trial is not submitted by the sponsor, it is strongly recommended that the sponsor be designated the contact for the trial's registry entry after the full trial details have been published, as the sponsor is best placed to make future updates (eg add trial results, link the registry entry to any future publications or registry entries, and add any generic name assigned to the investigational medicinal product). It is recommended that the arrangements for registration be described in a written agreement between the sponsor and delegate.

Guidance on prospectively registering a Category 1 trial with deferral of publication of all but limited details

The option to register a trial in ISRCTN with a minimal dataset applies only to trials with a deferral agreed by the HRA, whose guidance can be found under Research registration and research project identifiers - Health Research Authority (hra.nhs.uk). Deferrals allow the applicant to delay full registration of the trial (referred to as a Study on the ISRCTN site), and delay publication of the research summary by the HRA. Deferral applications are made

using new IRAS and deferrals will be granted only if you have not already registered the trial on any research registry.

Deferrals are initially granted for 12 months but can be extended every 12 months while the trial is ongoing, and then for up to 30 months after the end of the trial. Once the trial comes to an end, sponsors can ask to extend the deferral for up to another 30 months. Even if the deferral period has not ended, the HRA expects that the trial will be registered in full, and the research summary published in full, as follows:

- when the reason given for the deferral is no longer valid (for example, the trial is no longer commercially confidential for reasons such as the first summary results have been made public; or full details of the trial have been published in any research registry); or
- immediately, if the trial is terminated early for safety reasons.

Therefore, if you have a deferral in place on the grounds of commercial confidentiality but then register full details of the trial in **any** research registry, the justification for deferral is no longer valid, and you must inform the HRA. The HRA will publish a lay summary on the HRA research summaries website, and will expect the trial to be registered in full on ISRCTN or clinicaltrials.gov as follows:

- if a minimal dataset has been registered in ISRCTN, the trial must be fully registered in ISRCTN; or
- if a minimal dataset has not been registered in ISRCTN, the trial must be fully registered in ISRCTN or clinicaltrials.gov.

Please note that each registry entry in ISRCTN must reflect the whole trial protocol if it is to meet the WHO standards, which require complete, accurate and meaningful data for each item in the WHO Trial Registration Data Set at the time of registration. It is not possible to use ISRCTN to publish a minimal dataset for part of a trial and register full details of the rest of the trial in another registry. Only the following options are available in ISRCTN:

(1) the whole trial is registered in full in ISRCTN (and in other registries if the sponsor wishes); or
(2) the whole trial is deferred and a minimal dataset reflecting the whole trial protocol is published in ISRCTN, but full details of any part of the trial are not posted in any other research registry until full details of the whole trial are published in ISRCTN.

That is the case even if the commercially confidential part of the trial will be run in the UK and the rest of the trial will be run elsewhere. Sponsors should consider running commercially confidential parts of multi-part trials under a separate protocol.

All new trials must be registered before they start if the data generated in those trials are to be included in an application to an EU CA for a CTA or substantial modification made under the EU CTR. Trials registered in ISRCTN before they start enrolling are designated prospective registrations, whereas trials registered in ISRCTN after they have started enrolling are deemed retrospective registrations. For your registration to be deemed prospective, you must ensure that the trial has been published in ISRCTN on or before the date that you enter in the 'date of first enrolment' (previously called 'recruitment start date') field in the ISRCTN dataset; otherwise, your registration will be deemed retrospective and will not comply with Article 25. However, if registration occurs after the anticipated date of first enrolment that was submitted to ISRCTN but before the actual date of first enrolment you can ask ISRCTN to update the date of first enrolment to reflect the actual date of first enrolment. The change of date will result in the registration being designated prospective. For any change to the date of first enrolment that will change the registration designation from retrospective to prospective, ISRCTN will request evidence to support the actual date of first enrolment. Note that the date of first enrolment is the date of the first screening visit.

You must also provide all the required information at the time of registration and at the milestones outlined below.

The process for prospectively registering Category 1 trials with deferral of publication of some of the details is as follows.

1. Register for an ISRCTN account, if you do not already have one.
2. Enter your trial details as shown in Appendix B. Enter the appropriate 'deferral statement' into fields for which details will be provided at a later date (up to 30 months after the end of the trial).
3. Submit your trial, allowing time for it to be reviewed and published before the first screening visit. It is recommended that you make the submission just after you apply for MHRA/REC approval.
4. When ISRCTN confirms receipt of your data, respond via email according to the ISRCTN Application Form Guidance, as follows:
    - Quote your 5-digit reference number
    - Provide confirmation that the trial meets the criteria for Category 1 (pharmaceutical development clinical trials) in the EU clinical trial transparency rules. Say which

criterion it meets (*e.g. The trial falls into the following subcategory of Category 1 trials (pharmaceutical development clinical trials): Phase I clinical trials in healthy volunteers).* ISRCTN editors will confirm at this stage that the trial has been registered as a Phase I trial and will liaise with the registrant in the event that the HRA does not approve the deferral.

5. Await editorial review by ISRCTN (usually up to 2 working days), and respond as required.
6. Once the record is ready for publication, and you have provided the ISRCTN editor with written confirmation that the trial sponsor has agreed the final dataset, the ISRCTN editor will publish the record and you will receive an email to confirm the ISRCTN registration number.
7. The ISRCTN team will send reminders to prompt updates to the record and to check that contact details are still valid. These reminders will be adapted for deferred studies and will primarily ask for dates to be updated as appropriate. There is no need to respond to these reminders if the study record is up to date.
8. Provide the following updates (note that all new information will be posted alongside the original information, with the date). The following information **must** be provided to ISRCTN either by email to info@isrctn.com or using the online form 'Update your record'.

a. After review of the trial by the REC and MHRA, provide in the 'Ethics committee approval' field:

- the date and final decision on the trial application

b. Within 30 months after the end of the trial, provide:

- the sponsor trial code, if not already published (to be included in the 'Secondary identifying number(s)' field)
- the actual completion date of the trial (in accordance with the definition of the end of that trial that is given in the approved protocol)
- the total number of participants enrolled
- information for all deferred fields, any supplementary information as indicated in Appendix B, and corrections to any information that has changed since the start of the trial
- any other information the sponsor wishes to update (for example, the sponsor may wish to update the public title)

In addition, summary study results should be provided, ideally within 30 months after the end of the trial, to complete the WHO trial registration dataset. Submit results either by email to info@isrctn.com or using the online form 'Report your results', with appropriate attachments or links (eg to basic results on another registry, website or repository), as follows:

- a scientific summary of the study results (including participant flow chart and tabular summaries of: baseline characteristics, primary and key secondary outcome measures, and adverse events)
- an optional document containing a plain English summary of the results (a summary in plain language that should include the information specified in the HRA guidance Writing a plain language (lay) summary of your research findings - Health Research Authority (hra.nhs.uk))

  The scientific and optional plain English summaries of results will be published in the Study Outputs Table in the ISRCTN registry entry. Please note that it is not mandatory to post summary results of early phase trials, but it is considered best practice to do so.

c. Later during development of the investigational medicinal product, the nominated sponsor contact is to provide:

- summary study results (if not provided within 30 months after the end of the trial; see item b. above)
- URL to results/publications
- if required by sponsor: URL to protocol (published or unpublished) or a file that can be uploaded to the ISRCTN website and accessed by any user
- generic name of the investigational medicinal product (if available) or any other identifier, eg research code

Guidance on *retrospective* registration of Category 1 trials that started before implementation of the EU CTR

All clinical trial data included in an application for CTA or substantial modification made to an EU CA under the EU CTR must come from trials that have satisfied Article 25. For trials starting *before* the implementation of the EU CTR, Article 25 can be satisfied in the following ways:

- For trials that were wholly governed by the EU CTD, the entry in EudraCT is considered to meet the requirements for public registration, even for Phase I trials in adults that were not made public in the EU clinical trials register. So, international Phase I trials with sites both in the UK and the EU are considered to have been registered via EudraCT. That exemption from any requirement for further publication or registration also applies to UK-only Phase I trials in adults that finished before the end of the Brexit transition period (31 December 2020).
- For UK-only Phase I trials in adults that started before implementation of the EU CTR and had not finished by the end of the Brexit transition period (31 December 2020), the transparency requirements can be satisfied in one of two ways:

- publication in a peer-reviewed journal; or
- *retrospective* registration in a public register that is a primary or partner registry of, or a data provider to, the WHO ICTRP (registration after the trial has started).

Thus, UK Phase I trials that do not already satisfy Article 25 through publication, registration, or entry in EudraCT must meet the transparency requirements through publication or retrospective registration **if** the sponsor wishes to submit their data in applications made under the EU CTR. Those trials are:

- UK Phase I trials in adults, with no EU sites, that started under the EU CTD but had not finished by 31 December 2020
- UK Phase I trials in adults, with no EU sites, with a start date between 1 January 2021 and 30 January 2022

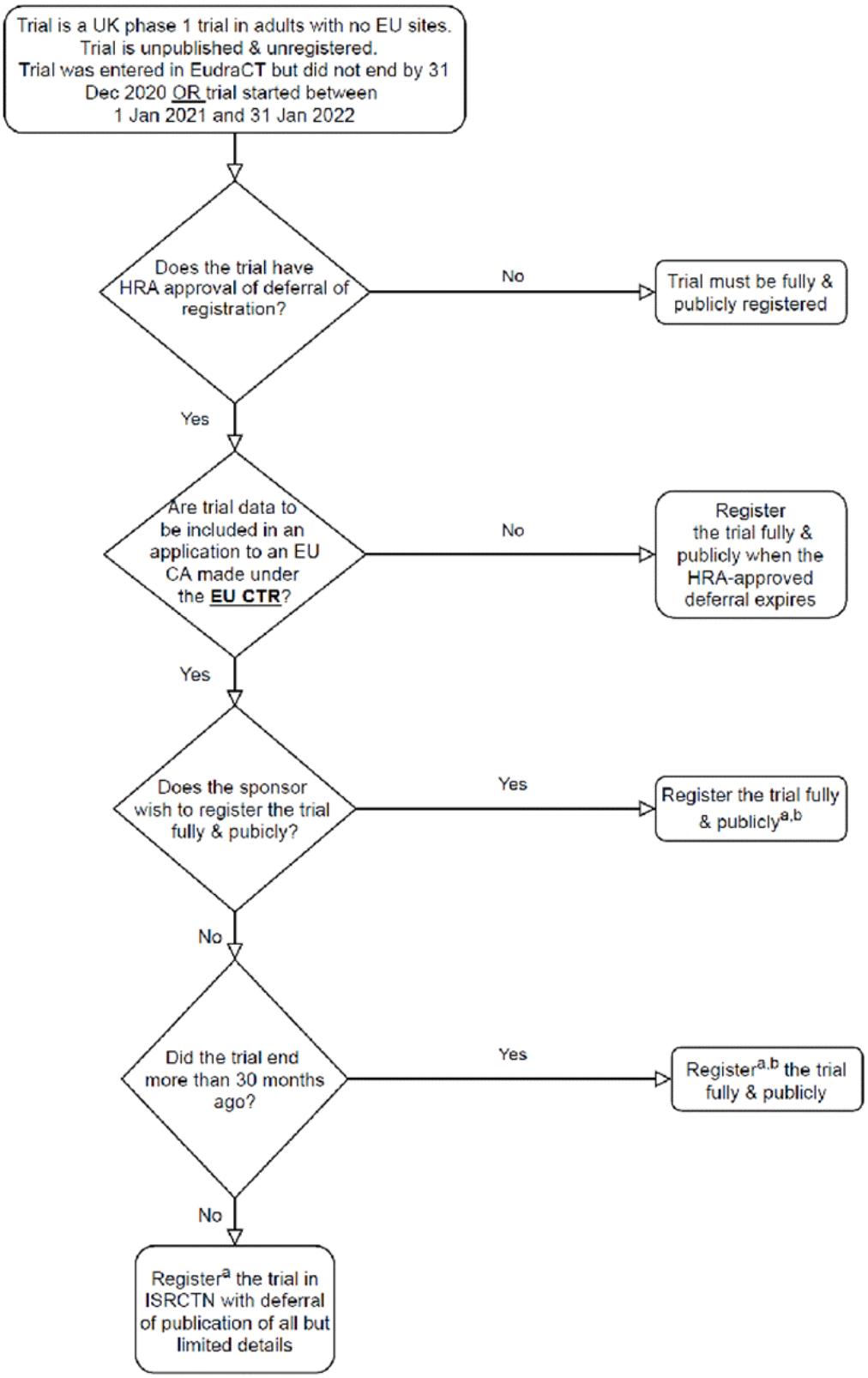
This guidance explains how to satisfy Article 25 through retrospective registration.

UK Phase I trials that have not been registered must hold HRA approval for deferral of registration. The trials must be registered fully and publicly when the HRA-approved deferral expires. However, if the HRA-approved deferral still applies:

- the trial data **can** be included in a UK application to the MHRA/REC
- the trial data **cannot** be included in an application made under the EU CTR to an EU CA, unless the trial is published or registered before the application is submitted

If a sponsor holds a valid HRA-approved deferral but needs to retrospectively register a UK Phase I trial in order to use the data in an application made under the EU CTR to an EU CA, ISRCTN allows sponsors to defer publication of all but limited details until up to 30 months after the end of the trial. However, if the trial finished more than 30 months ago, the trial must be fully registered.

The flowchart on page 8 summarises the requirements for retrospective registration of UK Category 1 trials.



a. To satisfy Article 25 of the EU CTR, the trial must be registered in a public register that is a primary or partner registry of, or a data provider to, the WHO ICTRP

b. Alternatively, the trial can be published in a peer-reviewed journal

If you wish to retrospectively register a Category 1 trial in ISRCTN and defer publication of all but limited details until up to 30 months after the end of the trial, follow the steps below.

1. Follow steps 1 and 2 of the above process for prospectively registering a trial, but note the following:
   - use the appropriate statement in Appendix B for deferred fields in trials registered after REC approval
   - include in your initial registry entry the details of REC approval
2. Make your submission.
3. Follow step 4 of the above process for prospectively registering a trial but attach to your email to ISRCTN evidence of the HRA's approval of deferral of clinical trial registration and publication of the research summary for your trial.
4. Follow steps 5, 6, 7, 8b and 8c of the above process for prospectively registering a trial and ensure that full trial details are provided within 30 months after the end of the trial.

Appendix A: Category 1 trials

The EU clinical trial transparency rules (*Revised CTIS Transparency Rules, EMA/263067/2023 dated 05 October 2023*) state the following:

'The categorisation of trials, as defined in the Appendix of disclosure rules, and that will remain in place under the revised CTIS transparency rules for CTIS, covers:

1. Category 1 trials - Pharmaceutical development clinical trials:

- Phase I clinical trial in healthy volunteers or patients;
- Phase 0 trial - in healthy volunteers or patients, without therapeutic or prophylactic intent;
- Bioequivalence and bioavailability trials;
- Similarity trials for biosimilar product including those conducted in patients where efficacy endpoints are used to determine biosimilarity, where pharmacokinetic and or pharmacodynamic studies are not possible;
- Equivalence trial for combination products or topical products where a pharmacodynamic or efficacy endpoint is used to determine equivalence, and where pharmacokinetic and or pharmacodynamic studies are not possible.'

The Appendix of disclosure rules referred to above is the *Appendix, on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited – EMA/42176/2014", EMA/228383/2015 dated 2 October 2015.*

Appendix B: ISRCTN dataset for a Phase I trial with deferred publication

The table below provides guidance on the data that should be submitted to ISRCTN for a UK Phase I trial with deferred publication. Information in red concerns updates that should be made after the initial record has been published. Deferred fields are shown in blue. One of the following deferral statements should be entered in deferred fields, as applicable:

- For registration before REC approval of the trial, include the following statement in deferred fields:
  The sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.
- For registration after REC approval of the trial, include the following statement in deferred fields:
  The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Again, please remember that once information is published within a study record, it cannot be removed. Even if changed, the previous contents will still appear in the study record's audit trail. Therefore, please ensure that you have removed any commercially sensitive information from the contents of the submission form before you press submit.

Field	Initial registry entry for deferred trials	Guidance for applicants
1. Study overview		
Initial information		
Responsible Registrant declaration	*Tick box to confirm that you are an appropriate representative of the study's primary Sponsor and that, as the Responsible Registrant, I*	

	understand my responsibilities.	
Does this study include participants from UK centres?	*Select 'Yes'*	Studies which do not include participants from UK centres are not eligible for the publication of a minimal record through a deferral.
Is this study interventional or observational?	*Select option*	Select option from: • Observational • Interventional This field is recorded as 'Study type' in the public record
Title & additional identifiers		
Registration number & date	*To be allocated by registry. ISRCTN staff will also add a marker for internal use to indicate that full publication of details is deferred.*	
Public title	Phase I trial: *[CRO/site name]* code: *XXX*	Give the public title as 'Phase I trial' and include the CRO/site code or another suitable identifier. The full public title may be added within 30 months after the end of the trial, if required by sponsor.
Scientific title	Phase I trial: *[CRO/site name]* code: *XXX* [The full scientific title will be published within 30 months after the end of the trial]	Give the scientific title as 'Phase I trial' and include the CRO/site code or another suitable identifier. Provide the full scientific

		title within 30 months after the end of the trial.
Study acronym		Leave blank. If applicable, details can be provided within 30 months after the end of the trial.
Secondary identifying numbers	IRAS *[IRAS Number]* *[CRO/site name code]* *[EudraCT/CTIS number]*	More than one Secondary identifying number can be added here. Provide the IRAS project ID number and another suitable identifier, such as the CRO trial code. Include the sponsor's protocol code if the sponsor agrees that it can be published; otherwise, provide sponsor code, along with any other trial identifiers (eg references to entries in any other public registers or databases), within 30 months after the end of the trial. Note that the deferral procedure cannot be used if the trial is publicly available with another registry such as clinicaltrials.gov.
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 will**

		be listed as PROSPECTIVELY registered; otherwise, it will be listed as RETROSPECTIVELY registered.
Date of final enrolment	dd/mm/yyyy	Enter planned date of the last visit of the last subject (as Phase 1 protocols usually allow withdrawn participants to be replaced, the last visit of the last subject is considered to be the date of final enrolment. Provide the actual date of final enrolment within 30 months after the end of the trial, or update the anticipated end date if necessary when prompted by ISRCTN.
Completion date	dd/mm/yyyy	Enter anticipated date of end of study. This is the anticipated date of last data collection (often last participant last visit). Provide the actual study end date within 30 months after the end of the study, or update the anticipated end date if necessary when prompted by ISRCTN.
Study design		
Allocation	*Select option*	Field appears for interventional studies only Select from:

		• N/A: single arm study • Randomized controlled trial • Non-randomized controlled trial For partially randomized controlled trials (randomization used in some parts of the trial), please select 'Randomized controlled trial'
Masking	*Select option*	Field appears for interventional studies only Select from: • Open (masking not used) • Blinded (masking used) For partially blinded trials (masking used in some parts of the trial), please select 'Blinded (masking used)'
Control	*Select option*	Field appears for interventional studies only Select from: • Placebo • Active • Historical • Dose comparison • None

Assignment	*Select option*	Field appears for interventional studies only Select from: • Single • Parallel • Crossover • Factorial • Sequential • Other (please state) If 'Other' is selected, [Deferral statement] may be added in place of details.
Purpose	*Select option(s)*	Field appears for interventional studies only Select from: • Treatment • Prevention • Diagnostic • Supportive care • Screening • Health services research • Basic science • Device feasibility • Other (please state) Selection of multiple options is permitted here.
Observational study design	*Select option*	Field appears for observational studies only Select from: • Case-control study • Nested case-control study

		• Case crossover study • Case series • Cohort study • Cross sectional study • Ecological study • Epidemiological study • Longitudinal study • Other (please specify)
Eligibility criteria		
Health condition(s) or problem(s) studied	Healthy volunteers *or* *[Deferral statement]*	Enter 'healthy volunteers' or, if the trial is a non-therapeutic trial in patients, enter the deferral statement and provide details (one phrase or sentence) within 30 months after the end of the trial.
Healthy volunteers allowed?	*Select option*	Select from: • Yes • No
Key inclusion criteria	Healthy human volunteer *Or* *[Deferral statement]*	For trials in healthy volunteers only, you can enter 'healthy human volunteer'. If the trial includes patients or requires healthy volunteers with specific characteristics (eg specific age ranges, ethnic origin), provide inclusion criteria (as a numbered list) within

		30 months after the end of the trial.
Lower age limit		Leave blank. Add lower age limit within 30 months after the end of the trial.
Upper age limit		Leave blank. Add upper age limit within 30 months after the end of the trial.
Sex	*Select option*	Select option from dropdown list: ● Both ● Female only ● Male only
Key exclusion criteria	Does not meet inclusion criteria *Or* *[Deferral statement]*	If the trial includes patients or requires healthy volunteers with specific characteristics (eg specific age ranges, ethnic origin), provide exclusion criteria (as a numbered list) within 30 months after the end of the trial.
Target sample size at registration	*[Number of planned participants]*	Enter the planned number of trial participants.
Final enrolment number		Leave blank, update with total final number of enrolled participants at a later date.
Study description		
Study objectives	*[Deferral statement]*	Provide details within 30 months after the end of the trial.
Interventions / Methodology	*[Deferral statement]*	Provide details of treatments, randomisation, route and duration within

		30 months after the end of the trial.
Intervention type	*Select option*	Interventional study only Select option from dropdown list: ● Not specified ● Drug ● Supplement ● Device ● Biological/vaccine ● Procedure/Surgery ● Behavioural ● Genetic ● Other ● Mixed
Phase	*Select option*	Select option from: ● 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 within 30 months after the end of the trial.
Primary outcome(s)	*[Deferral statement]*	Provide details within 30 months after the end of the trial.
Key secondary outcomes	*[Deferral statement]*	Provide details within 30 months after the end of the trial.
2. Information for participants		
Plain English summary of protocol	*[Deferral statement]*	Provide a lay summary within 30 months after the

		end of the trial. Include in the summary these subheadings: Background and study aims Who can participate? What does the study involve? What are the possible risks and benefits of participating? Where is the study run from? When is the study starting and how long is it expected to run for? Who is funding the study? Who is the main contact?
Countries of recruitment	*Select option*	Select country/countries from the search list.
UK study participating centres		Create a Study Centre for each site
Study participating centre outside UK		Optional field. If relevant and desired, create a study centre for each site outside the UK.
3. Contacts, sponsor, funder, ethics		
Contact for Public Queries **Contact for Scientific Queries** **Principal investigator**	*[Name of contact]* *[ORCID ID]* or leave blank *[Professional Address, City, Country, Zip/Postcode]*	You must enter three contacts: the Principal Investigator (PI), a scientific contact **and** a public contact. The PI must be named, but the scientific and public contacts can be identified by role or department. The scientific and public contacts can be

	[Enquiries telephone number] *[Enquiries email address]*	the same person/role/department, and the PI can serve as each of the three contacts. NB: In IRAS, the investigator responsible for the entire study is called the 'Chief investigator'; however, this role is 'Principal investigator' in the WHO International Standards for Clinical Trial Registration, which is the standard used in the ISRCTN registry. You will be prompted to provide the following information for each contact: *Title, First Name, Last Name* Select title and enter name. This is mandatory for the PI, but optional for the scientific and public contacts. For the scientific and public contacts, include a role or department name here if the contact is not a named person. For example, for the scientific or public contact, you could select 'Dr' as title, and

		enter ‘Project Management’ as first name, and ‘Department’ as surname *ORCID ID* Enter if available; otherwise, leave blank. *Address* Enter the professional address of the contact. *Tel* Enter telephone number (a general enquiries number is strongly recommended) *Email* Enter an email address for enquiries (a general enquiries email address is strongly recommended)
Primary sponsor	*[Name of primary sponsor organisation]*	Enter name of primary sponsor organisation
Secondary sponsor	*[Name of secondary sponsor organisation] or leave blank*	Optional field. If there is a secondary sponsor organisation, enter its name here.
Funder organisation	*[Funder organisation]*	Enter name(s) of funder organisation or sources of monetary or material support (which may be the same as the sponsor).

Ethics approval required	*Select option*	Select option from dropdown list: • Ethics approval required • Ethics approval not required
Ethics approval status	*Select option*	Select option from dropdown list: • Not yet submitted • Submitted • Approved
Ethics committee approval – Status date	*Date formatted dd/mm/yyyy*	If the trial has not yet been approved, provide date of submission to the MHRA and REC. Provide the date of approval, when available and ideally before the trial starts. If the trial has been approved, provide date of approval by the MHRA and REC.
Ethics committee approval – Ethics committee name	*[REC name]*	Provide the name of the REC the trial has been submitted to or approved by.
Ethics committee approval - Address	*[REC street address]*	Provide the street address of the REC the trial has been submitted to or approved by.
Ethics committee approval - City	*[REC City]*	Provide the city of the REC the trial has been submitted to or approved by.

Ethics committee approval - Country	*[REC Country]*	Select 'United Kingdom'
Ethics committee approval – Postcode	*[REC Postcode]*	Provide the REC's postcode
Ethics committee approval - Telephone	*[REC contact telephone number]*	Provide the REC's telephone number, if present
Ethics committee approval – Email address	*[REC email address]*	Provide the REC's email address
Ethics committee approval – Reference number	*Ref: [REC reference number]*	
4. Uploads and Outputs		
Third-party confirmation	*Upload file at submission or tick 'Third-party confirmation of study to be sent later'*	If there is already evidence from a third-party confirmation that the study exists (for example a letter from the REC, funding agency or government regulatory authority), this can be uploaded and attached to the submission form here. You can use your validation letter from the REC/MHRA or a screenshot from IRAS showing the IRAS ID and confirmation of submission, provided that it includes IRAS project ID number. Although the document will not be made public by ISRCTN, you may wish to redact details such as the trial study title and sponsor

		protocol code, to preserve confidentiality. If evidence from a third party does not already exist, you can send this to info@isrctn.com as soon as you have this available. ISRCTN will record that this information has been provided and store the document, but the evidence will not be publicly displayed.
Do you plan to share individual participant data?	*Select option*	Select option from: • Yes • No
Individual participant data (IPD) sharing plan	Conditional field, appears if answering yes to 'Do you plan to share individual participant data?' *[Provide plan]*	Provide a plan for the availability of de-identified participant data (raw data) or a statement if the sponsor will make the data sharing plans available at a later date. If the sponsor will make the plans available at a later date, ISRCTN will ask for a data sharing plan to be added at a later date.
Do you wish to upload anything else?	*[Provide any other files intended for upload at this point]*	Optional field Uploads could include Participant information sheet or publication and dissemination plan

5. Payment Agreement		
Payment method	*Funded registration*	Select 'Funded registration' from the dropdown list
Why did you choose ISRCTN to register your study?	*Optional: there is no need to answer this question.*	Optional field If you choose to answer this question, you can select 'Other (please specify)' from dropdown list and enter 'Deferral'