ISRCTN registry

Application form guidance

This document includes the definitions and explanation of the data fields to be completed when submitting a record for registration on ISRCTN. The information requested is based on the definitions and set requirements for trial registration from the International Committee of Medical Journal Editors (ICMJE) and World Health Organization (WHO) Trial Registration Data Set. Definitions of terms used are available at the ISRCTN definitions page.

To ensure your study is registered as soon as possible, please refer to the Rapid Registration Checklist at the end of this document.

* = Mandatory data items for trial registration with ISRCTN.

Part 1. Trial Details	
> Title & Additional Identifiers	
Public title*	We expect the public trial title to contain enough information so that the main aim of the trial is easily understood by the public. The public title is usually used for the general public and may be the title given on patient information sheets. It should be brief but contain enough information so that a member of the lay public would easily understand the main aim of the study. Please note that the public and scientific titles should not be the same.
Scientific title*	The scientific title is intended for use in grant and ethics applications. It should be in the PICO format, containing information on the Participants in the trial, its Intervention(s) and the Comparisons and Outcomes of the trial. If you use an acronym for your study, use upper case for the corresponding letters.
Acronym	An abbreviation of your scientific title. This can be made up from individual letters from your title or parts of a word from your title. Alternatively, you can supply a short name that you use to refer to your study.
EudraCT number	If your trial is also registered in the European Union Drug Regulating Authorities Clinical Trials Database (EudraCT) and you have a unique EudraCT number, enter it here. The format is YYYY-123456-78.
IRAS number	If your study has an IRAS number, enter it here.
ClinicalTrials.gov number	If your trial is also registered in ClinicalTrials.gov, enter the number assigned to your trial here. The format is NCT12345678.
Protocol /serial number*	This is for the internal reference given to the study by the researcher, the funder or sponsor etc. You can enter the trial ID here if you have registered your trial in any other registry. UK studies, if you have a CPMS number please enter it here. The format is CPMS 12345
> Study Information	
Study hypothesis*	The principal questions or hypotheses addressed by the study. Hypotheses are best suited to interventional trials, and are statements

	that may be proved or disproved as a result of the study. For example, a hypothesis might be "Drug X reduces blood pressure more than Drug Y". For observational trials, if no hypotheses are available, please enter the aims of the study. Multiple hypotheses or aims should be in a numbered list.
Ethics approval*	Please provide the name of your ethics board (providing an English translation of the name if appropriate), their contact details (postal address, telephone number and email address), the date of approval in an 8-digit format (DD/MM/YYYY), and any reference numbers attached to this approval. If you have no ethics approval yet, then please enter details of when and with whom you plan to submit. If your study does not require ethics approval, please tell us why.
Study design*	Please briefly describe, in one sentence, the study design for your trial. If interventional, please include details about allocation, masking, control and assignment. Please also specify whether the study is single-centre or multicentre. If observational, please also include details about the duration and type of study (e.g. cross-sectional cohort study, longitudinal case-control study).
Primary study design*	Please select from the drop-down menu whether your study is observational or interventional.
Secondary study design	Please select the study design that most accurately describes your trial from the drop-down. If the study design is not shown, choose 'other' and enter the design below.
Trial setting*	Studies can be run from a variety of different settings. Select where the study will take place from the drop-down. View the list here.
Trial type*	A study can be classified by its purpose, that is, by the reason why it is taking place. Please select the option that most accurately describes your study's purpose from the drop-down. View the list here.
Overall trial start date*	A study starts when you begin planning the design of the study and developing the protocol. The overall start date should be before ethics approval, funding and the recruitment start date. The correct format is dd/mm/yyyy.
Overall trial end date*	The end date of your study. In many cases, it is the last date that data is collected. The correct format is dd/mm/yyyy.
Condition*	Please specify the name of the disease, condition, or healthcare domain being studied. If you would like to add more information on the disease being studied, then this information can be placed in the plain English summary section.
Interventions*	**For interventional trials**, please provide a brief methodology for each of your study arms, giving a summary of the treatment given to each group applicable (name, dose, how it is administered), the total duration of treatment and follow-up for all study arms, as well as details of the randomisation process if applicable (e.g. sealed envelope, etc.). **For observational trials**, please provide a simple and brief methodological description of what happens to participants taking part in this trial (from enrolment to the end of their participation), including the total duration of observation and the total duration of follow-up.

	Please write in the third person and present or future tense.
Intervention Type	Please select the intervention type from the drop-down that most accurately describes that used in your trial. View the list here.
If Drug, Device, or Biological/Vaccine selected for Intervention Type:	
Phase	Drug, device, and biological/vaccine trials are commonly carried out in a series of phases. Please select which option is appropriate from the drop down or select 'Not applicable'. View the list here.
Drug name(s)	If the intervention uses one or more drugs or biologicals then use the international non-proprietary name (INN) for each drug or other generic name if possible (not brand/trade names). For an unregistered drug, the generic name, chemical name, or research code is acceptable. For devices and vaccines, use the trade name or research code.
Primary outcome measure*	The primary outcome measure of a study is the data, or result, from which the main aims of the clinical trial can be assessed. It can be used to decide whether a hypothesis has been proven or principal question answered. Please enter the primary outcome measure, the method used to measure (specific name required if medical test or questionnaire), and the exact time points at which the outcome will be measured. The correct format is: Pain is measured using a visual analogue scale (VAS) at baseline, 24, 48, and 72 h
Secondary outcome measures*	The secondary outcome measures of a study are the data, or results, that answer questions relevant to the study but secondary to those assessed by the primary outcome measures. Please enter a numbered list of the key secondary outcome measures, the method used to measure each outcome, and the exact time points at which each outcome will be measured. 1. [Outcome A] measured using [method B] at [time C] 2. [Outcome X] measured using [method Y] at [time Z]
Trial website	If available, please give the URL of the trial website (including http:// or https://). This field should only contain websites developed specifically for the trial; the website of the sponsor organisation can be included in the sponsor section.
Participant information sheet	The participant information sheet (PIS) should state the aims of the study and what the participants will be asked to do in plain English. Please include the URL if it is web-based or downloadable from an internet site. If you wish to make your PIS only accessible to the participants taking part in the trial, please write "Not available in web format, please use contact details to request a participant information sheet". If your study does not require a participant information sheet, please write "Not applicable". If you would like to upload your PIS to the trial record please refer to the checklist at the end of this document for how to do this.
> Eligibility	
Participant inclusion criteria: Participant type	Participant inclusion criteria are a list of characteristics that all potential participants must have to take part in the study. Please select the type

	of participant taking part in this study from the drop-down. View the list here.
Participant inclusion criteria: Description*	Provide a numbered list of all the characteristics that all potential participants must have to take part in the study, including age range.
Participant inclusion criteria: Age group*	Please select the age group of your participants from the inclusion criteria as listed in the drop-down. View the list here.
Participant inclusion criteria: Gender*	Please select the gender of the participants taking part in your study from the drop-down.
Participant inclusion criteria: Target number of participants*	This is the target total recruitment of participants for the trial (across all arms and all sites if a multicentre trial). If your study is a cluster randomised controlled trial, please include the number of clusters and how many participants are included on average in each cluster.
Participant exclusion criteria*	Provide a numbered list of the characteristics that exclude potential participants from taking part in the trial. Do not include the opposite of your inclusion criteria.
Recruitment start date*	The date, or planned date, of recruitment of the first participant to the study, i.e. first participant in. If your data is historical, please use the date that you will start collecting data from records as the recruitment start date.
Recruitment end date*	The end date, or planned end date, of recruitment of participants for the trial, i.e. last participant in.
NOTE: **Prospectively registered/ Retrospectively registered**	When your study is listed on the ISRCTN registry, the record will have a 'Prospectively registered' or 'Retrospectively registered' flag. This flag is calculated by comparing the 'recruitment start date' with the 'date assigned' (the date of registration). The registration process (i.e. application, response to editorial queries, and **payment of the registration fee**) must be completed before the recruitment start date to ensure your study is prospectively registered. Note that studies paid for using the 'online' method will be published immediately upon payment. Studies paid using bank transfer will take at least seven days to be published once payment has been made.
> Locations	
Countries of recruitment*	Please select all the countries where recruitment for the study is expected to take place. If you are registering a study taking place in the UK NHS, it may be eligible for inclusion in the NIHR portfolio database. Please click here for further information.
Trial participating centre*	A trial may take place in many countries and have many participating centres/sites. Enter the name and address details of all participating centres/sites where the trial recruits, submitting the details of the lead centre first. You can add another centre by clicking on "Add another centre. Please include details of all sites where the research is taking place rather than where it is administered from.
> Name*	The name of the institution (e.g. hospital, university, etc.). For NHS sites in the UK, enter the first few characters of the name and select from the list to auto-complete all fields.

> Address	The street address (include the department, faculty, or NHS trust here, **not** in the name field). The state or county can also be included here.
> City	The city.
> Country*	The country.
> Post/Zip code*	The post/zip code (if there is no code, enter a hyphen [–] in this field).
> Plain English Summary	
Plain English Summary*	The plain English summary describes your research to the lay public and should be written in easily understood plain English in 1000 words or fewer. Please include all of the following subheadings (further guidance here): *Background and study aims* *Who can participate?* *What does the study involve? (for participants)* *What are the possible benefits and risks 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?*
> Results and Publications	
Publication and dissemination plan	Please briefly outline any future plans for publication and dissemination of your study results. If your exact plans are unknown at this stage, we would suggest using a general statement, such as "Planned publication in a high-impact peer-reviewed journal". You should also include an IPD sharing statement in this field (see the checklist at the end of this document)
Intention to publish date	Please give a date for when you expect to publish the full results of your study. If your exact plans are unknown at this stage, we would suggest using one year after your overall trial end date.
Individual participant data (IPD) sharing statement*	Please add your plan for sharing participant-level data (sometimes referred to as raw data). For further information on the details required please click here.
IPD sharing summary*	The purpose of this field is to summarise your plans for sharing participant-level data (sometimes referred to as raw data), matching the individual participant data (IPD) sharing statement. Please select the most appropriate option(s).

Part 2. Contact	
> Contact	
Type*	The principal investigator is the person responsible for leading the trial. (In the UK this person is known as the chief investigator). The scientific contact is the person who will respond to scientific queries about the study. The public contact is the person who will respond to general queries, including information about the current recruitment status. At least one of each type of contact must be added (these can be the same person) by clicking on "Add another contact".
Title*	
First name*	
Last name*	

ORCID ID	An ORCID ID is a unique digital code for researchers that can be used to identify all their publications and grant applications. If you are interested in obtaining one, go to the ORCID website for further information.
Address*	The name of the institution and street address. The state or county can also be included here.
City*	The city.
Country*	The country.
Zip/Postcode*	The post/zip code (if there is no code, enter a hyphen [–] in this field).
Tel*	An institutional telephone number must be used (if available). Add international calling code.
Email*	An institutional email address must be used (if available).

Part 3. Sponsor & Funder

> Sponsors	
Sponsor **Organisation*** **Address*** **City*** **Country*** **Zip/Postcode***	The sponsor is the organisation (rather than an individual) taking primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. Enter the first few characters of the sponsor institution and select the correct name from the drop down list. If the name is not available please enter the full name of the institution. Add more sponsors by clicking on 'Add another sponsor'.
Tel*	Should not be the same as the study contacts'. Add international calling code.
Email*	Should not be the same as the study contacts'.
Type	Select the appropriate type from the drop down menu.
Website	Including http:// or https://
> Funders	
Funder **Funder name**	All studies need funding even if they are self-funded. Please list all the funders for this study, providing an English translation for names of institutions/organisations as appropriate. You can use the FundRef functionality to select the names and contact details of major funders. If the name of your funder does not appear in the list, input it manually. Please enter "Investigator initiated and funded" if self-funded. If your sponsor is paying for incidental costs incurred by the trial during its lifecycle, please list them as the funder of the trial. You can add another funder by clicking on "Add another funder".

Part 4. Payment

After your trial registration has been curated by our in-house editorial team, you will be required to pay a one-off fee of GBP 226 +VAT when applicable for registering a study with an ISRCTN. This fee

helps to cover the cost of editing and curation, data conversion, and permanent online hosting. Prompt payment is advised as the ISRCTN will not be assigned and the record will not be published until payment is received.	
> Payment method	
Payment method	Choose whether you wish to make an online payment using a credit or debit card (this method means that the trial record will be published immediately on payment) or an offline payment (we will send an invoice and your institution can pay by bank transfer). Offline payment costs an extra GBP 20 to cover administration costs and may mean a delay to trial registration. The 'funder pays' option is only for UK-based studies where the funder has an agreement with ISRCTN.
> Invoice details (if offline payment selected)	
First name*	Enter the contact details of where you would like the invoice to be sent. Please note that an invoice will not be generated until you have been informed that your record is ready for publication by a member of our editorial team.
Last name*	
Institution	
Address*	
City*	
Zip*	
Country*	
Email	
Purchase order number/reference numbers	If this application is funded by your institution, you may need a purchase order (PO) from the finance department before an invoice can be paid. Check with them and enter the reference our invoice should quote in this field.
VAT number	Getting a trial ID may be subject to VAT (value added tax or sales tax) depending on the applicant's country. Enter the relevant VAT identification number in this field.

Rapid Registration Checklist

If you would like to register your trial as quickly as possible please take note of the following:

- Ensure that the public title is in the required format.
- Ensure that the 'interventions' field contains all of the required information.
- Ensure that the primary and secondary outcome measures are in the required format.
- Ensure that all of the dates are entered as specified above.
- Select the online payment option and be prepared to make payment once you have been notified that your application is ready to publish.
- After you have submitted your application and received a confirmation with a 5-digit reference number, please respond to the confirmation email including the information below:

□ ISRCTN is required under the WHO standards for trial registration to obtain written third-party confirmation that a trial exists. Acceptable evidence includes letters from ethics committees, funding agencies or government regulatory authorities. We will record that this information has been provided and store the document, but the evidence will not be publicly displayed. Please send written third-party confirmation as an attachment.

□ With reference to the June 2017 ICMJE data sharing statement for clinical trials, could you also please specify whether additional documents (such as study protocol, statistical analysis plan etc.) are or will be available?
If the protocol is already published and/or is available online, please provide the reference and url. Alternatively, ISRCTN can upload a copy of any additional documents to your study record. A protocol can be uploaded on the understanding that it will not be peer-reviewed and will be treated as a pre-print and that most journals are likely to consider that such a posting would not preclude any subsequent protocol publication in a peer-reviewed journal. Please send any documents you would like to be uploaded to the study record as an attachment.

□ We regularly tweet about clinical trials using the @ISRCTN Twitter account. If you would be interested in being tagged in any tweets about your trial, please provide Twitter handles for any relevant trial contacts, sponsors, funders and/or the study's Twitter profile, or let us know if you do not wish your trial to be tweeted by us.

□ If you are interested in writing a blog about your trial for the BMC blog network, please let us know by contacting info@isrctn.com.