Adding Study Details to Public Databases

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Version	Date	Reason for Change
Version 1.0	31 May 2007	Annual review
Version 2.0	25 Jun 2008	Annual review
Version 3.0	08 Feb 2010	Formation of Joint Research Compliance 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	31 Jul 2019	Administrative changes and clarifications to the process
Version 9.0	19 March 2020	Clarifications to the process.
Version 10.0	19 Oct 2020	Scheduled review Template removed and administrative changes to SOP JRCO name change to RGIT.
Version 11.0	07 Jan 2021	Amendments due to leaving the European Union from 1st January 2021
Version 12.0	01 Feb 2022	Amendments due to the partnership between the HRA and

		ISRCTN registry commencing from 1st January 2022

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1. PURPOSE

This standard operating procedure (SOP) describes the process for registering, adding study details, maintaining study records and reporting results on public access databases.

2. INTRODUCTION

The World Medical Association Declaration of Helsinki states that "every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject" and the International Committee of Medical Journal Editors (ICMJE) considers clinical trials for publication only if registered in an appropriate registry.

It is a best practice expectation that all research should be registered in a publicly accessible database. *However, f*or clinical trials, it is a condition of a favourable ethical opinion to do so. Since September 2013, the registration of clinical trials has been a formal condition of NHS Research Ethics Committee (REC) approval, in line with researcher and sponsor duties as set out by the WHO, current Declaration of Helsinki and the UK Policy Framework for Health and Social Care. Registration should occur before the first patient is recruited.

Clinical trial registration and reporting helps to prevent selective publication and selective reporting of research outcomes, to prevent unnecessary duplication of research effort, and to help patients and the public know what trials are planned or ongoing.

2.1. Definition of a Clinical Trial
'Clinical trials' are defined as all studies which fall into the first four categories of question two on the Integrated Research Approval System (IRAS) filter page. (Cited 23 June 2020) These are:
- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an Investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration.

2.2. Applicable Studies
All clinical trials must be registered on a publicly accessible database, however there are a few options for which database to choose. Irrespective of the database selected, there are general guidelines that need to be followed, most importantly that the results need to be reported within 12 months from the submission of the end of study notification (or within 6 months for paediatric trials). **Results need to be reported within this timeframe regardless of the study outcomes and regardless of the publication status.**

The International Committee of Medical Journal Editors (ICMJE) requires and recommends that all medical journal editors require registration of clinical trials in a public trial registry at or before the time of first patient enrolment as a condition of consideration for publication.

If your research falls into the definition of a clinical trial, you must make sure you register your study BEFORE enrolment of the first participant; otherwise you may not be able to publish.

When registering your study, you will need to pre-specify all outcomes that will be measured (e.g. weight, blood pressure, survey measurements) on the public database you choose. Once the trial is complete, you should report all pre-specified outcomes. Where reported outcomes differ from those pre-specified, this must be declared, along with an explanation of the timing and reason for the change. This ensures a fairer picture of the trial results.

The RGIT reserves the right not to issue sponsorship if a chief investigator currently has outstanding final reporting to undertake after the 12-month deadline.

2.3.   Recommended Registry

A 'public registry' is defined as any register on the WHO list (Cited 23 June 2020), of primary registries or the ICMJE list (Cited 23 June 2020), of registries.

There are several registries that meet the ICMJE criteria as an acceptable trial registry, but the RGIT predominantly works with and tracks ClinicalTrials.gov, ISRCTN and for CTIMPs running in the EU, EudraCT. Therefore, it is recommended that you use one of the registries mentioned above, depending on your situation. You should select the appropriate registry for your study based on the requirements and your preferences.

Additionally, the funding body or the research ethics committee for your study may have their own requirements or preferences about which registry to use.

- ClinicalTrials.gov is a registry and results database of publicly and privately supported research studies conducted in the United States and around the world.
- International Standard Randomised Controlled Trial Number (ISRCTN)accepts all studies involving human subjects or populations with outcome measures assessing effects on human health and well-being, including studies in healthcare, social care, education, workplace safety and economic development.
- EudraCT (European Union Drug Regulating Authorities Clinical Trials) is the European Clinical Trials Database of all CTIMPs with at least one site in the European Union (**predominantly for CTIMPS started prior to January 1, 2021**).

If a study is already registered on one database, it is unlikely that it would need to be registered on others. Please check with the RGIT before registering on multiple databases. **If you do decide to register on multiple databases, you will need to maintain both records and post results on both sites** (which require different levels of information and have different reporting templates).

Reporting results on ClinicalTrials.gov, ISRCTN or EudraCT does not count as prior publication, thus 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.

2.4.   Clinical Trials Ａfter January 1, 2021

Starting from 1 January 2022, all CTIMPs that are submitted to the Health Research Authority (HRA) using the IRAS combined review service will be automatically registered on

ISRCTN. The studies will be registered using data from the HRA's systems, therefore trialists and sponsors will not have to apply for registration separately. There is no charge to sponsors or researchers for automatic registration under an agreement between the HRA, the Department of Health and Social Care and the ISRCTN registry.

Imperial sponsored non-CTIMP clinical trials, beginning on or after January 1, 2022, now have the option to register their studies on either ISRCTN or Clinicaltrials.gov depending on study team preference and funding.

For CTIMPS, studies will be automatically registered with ISRCTN, however they will still need to get a EudraCT number. CTIMPS will need to follow the steps outlined below, in section 3, for acquiring a EudraCT number, but they will not report their results on EudraCT.

2.5. **Clinical Trials <u>Before</u> January 1, 2021**

For CTIMPS registered on EudraCT which began before 2021, you will still need to report results on EudraCT. After January 1, 2021, the MHRA will no longer have the ability to update information on EudraCT so you will need to email the MHRA when you have reported results on EudraCT by following the steps below:

- You must send a short confirmatory email to CT.Submission@mhra.gov.uk. The subject line of the email notification must state 'End of trial : result-related information: EudraCT XXXX-XXXXXX-XX' once the result-related information has been uploaded to the public register and provide a link. If your clinical trial is not on a public register, summary results should be submitted by email to CT.Submission@mhra.gov.uk. An acknowledgement letter will not be sent for this submission.
- You should also submit a final report to the Research Ethics Committee within the same timeframe for reporting the summary of results.

3. EUDRACT

EudraCT (European Union Drug Regulating Authorities Clinical Trials) is the European Clinical Trials Database of all CTIMPs with at least one site in the European Union.

A EudraCT number is required in order to apply to the Medicines and Healthcare products Regulatory Agency (MHRA) for a Clinical Trial Authorisation (CTA) and to apply for REC approval of your clinical trial. CTIMPS which began before 2021 will still need to register and report results on EudraCT. CTIMPS beginning on or after January 1, 2021, will only need to apply for a EudraCT number, but not report results on EudraCT.

3.1. **Getting a EudraCT Number**

Application for EudraCT Number:
<u>Send an email to the Research Integrity Officer</u> providing the information requested below:

- Requestor's organisation name: Imperial College or Imperial College Healthcare NHS Trust
- Contact information (e.g. name and email address):
- Sponsor's protocol code number:
- Is it anticipated that this EudraCT Number will be used for a clinical trial contained in a Paediatric Investigation Plan (PIP)?

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- Is it anticipated that this EudraCT Number will be used for a clinical trial conducted in a third country (outside of the EU/EEA)?
  - If so, which member states is it anticipated that the trial will be run?
  - If not, which EU/EEA member states do you expect the trial to run in?

You should receive a response within three working days. Once the EudraCT number has been created, it will be forwarded to you. When the EudraCT number is forwarded to you, you will also receive a template which shows you the type of information that will need to be collected in order to report the results. Reviewing this template and making a plan to record the needed information will help you to report results in the future. The template can also be found in appendix 7.1.

3.2. Maintaining your EudraCT Record

For CTIMPS which started prior to 2021, entries on EudraCT are made up of information uploaded by the national competent authority (NCA) in EU member states. In the UK the competent authority is the MHRA.

If you need to make changes to this information, including changing the study end dates or reporting a failure to recruit patients (so that a note can be added to the registry entry to explain that no results should be expected)**, it needs to be done through the national competent authority that originally authorized the trial.** Results information is the only information a researcher can add to EudraCT directly. For everything else the information must go through the national authority.

3.3. Reporting Results on EudraCT

Reporting results on EudraCT within one year of study completion (and within six months for paediatric trials) is a legal requirement for studies which began before 2021.

Prior to the reporting deadline, the person responsible for uploading the study results should do the following:

1. Create an account on EudraCT (instructions for creating this account can be found in appendix 7.2)
2. Become a results user (instructions on becoming a results user can be found in appendix 7.2)

Once the account has been created and results user status has been received, you will need to send an email to the Research Integrity Officer requesting reporting access for your trial. Please include your EudraCT number and EudraCT account username in the email. Once the Research Integrity Officer has this information, they will designate you as the back-up user for the trial and you will be able to log in and post results. Once the results have been posted, it takes at least 14 days until the record becomes public.

When finished, you must send a short confirmatory email to CT.Submission@mhra.gov.uk once the result-related information has been uploaded to EudraCT, with 'End of trial : result-related information: EudraCT XXXX-XXXXXX-XX' as the subject line.

The Research Integrity Officer will remain the primary user in order to help troubleshoot, if needed.

In some circumstances it is possible to upload a summary of the results in document form, for example a journal article or the synopsis section of a clinical study report. This is only an option for trials that ended on or before 21 July 2013. Trials ending after 21 July 2013 will need to fill in the full table of results information.

EudraCT has created guidance and provided definitions related to posting results, please see appendix 7.3.

The RGIT has created a template of the type of information required for results reporting, which may be useful to review. Please see appendix 7.1.

Studies that fail to post results on time are monitored and tracked on a variety of publicly accessible websites, including those below. **Not posting study results on time has a negative effect on Imperial as a sponsor and goes against Imperial's commitment to research best practice and transparency.**

- EU Trials Tracker for Imperial College London (Cited 23 June 2020)
- EU Trials Tracker for Imperial College Healthcare NHS Trust (Cited 23 June 2020)
- EU Trials Tracker for Imperial College London and Imperial College Healthcare NHS Trust (Cited 23 June 2020)

4. CLINICALTRIALS.GOV

ClinicalTrials.gov is a publicly accessible database, which is free to register details of your clinical trials. It will accept any trial that meets the ICMJE definition of a clinical trial, regardless of where the trial is to take place. Before registering your study on ClinicalTrials.gov, please note the following conditions:

1. **If you want to register a study on ClinicalTrials.gov, you will need to post the study results on the website within one year of study completion, regardless of outcomes of the study and regardless of the publication status**. Once the study has been entered onto ClinicalTrials.gov it becomes part of the public domain and we need to ensure results are reported, in accordance with best practice and in light of increased awareness and scrutiny around transparency.
2. **Once your study has been registered, you must log into ClinicalTrials.gov and verify that the information on record is still accurate at least every 6 months.**
3. **If your study is registered on EudraCT, it does not need to be registered on ClinicalTrials.gov as well, unless any of the following applies:**
   - The study has a site in the USA.
   - The study is evaluating a drug, biological, or device product which is regulated by the United States Food and Drug Administration.
4. **If your study is automatically registered with ISRCTN by the HRA, it does not need to be registered on ClinicalTrials.gov unless you need to do so to meet requirements set by other organisations or regulatory bodies for your trial.**
5. **If you do decide to register on multiple registries including ClinicalTrials.gov, you will need to maintain all records and post results on all the sites** (which require different levels of information and have different reporting templates).

4.1.   Registering on ClinicalTrials.gov

The Research Governance and Integrity Team is the designated 'Administrator' for registering users on ClinicalTrials.gov.

As administrator, we will create a user account for you (upon request), giving you access to register trials on the system. We will check and release records for ClinicalTrials.gov to review once you have completed them properly. If you would like a user account, send an email to the Research Integrity Officer requesting an account to register your trial.

- Once the Research Integrity Officer has created an account for you, your log in details will be sent to you automatically from ClinicalTrials.gov via email and you will be able to register the trial.

4.2. Maintaining your ClinicalTrials.gov Record

Once your user account is created, you will be able to enter information about clinical trials online.

To Log In:
- Visit the PRS registration site (Cited 23 June 2020)
- Complete the three fields on the login screen (as provided to you in the automatic email notification after your account was created):
    Organisation: **ImperialC** or **ImperialNHSTrust** (depending on which organisation is sponsoring the study)
    Username: user login name
    Password: (case-sensitive)

To Create a Record:
A record may be created at a single session or created and saved for completion later. To create a record during a single session:
- Follow [Create] from the Main Menu screen. Choose "New Record"

- To create a record and save for completion later, use [Quit] to stop data entry after step b (above), or any other successive screen. Then use [Save Protocol Record] to keep your data. The record will be saved for later.

Information must be correct and readily understood by members of the public. **You are required to update each clinical trial record every six months.**

Please update the "Record Verification" to that day's date every time you login or update your record.

4.3. Reporting Results on ClinicalTrials.gov

These procedures are based on those provided by ClinicalTrials.gov. For more information on procedures and on the database's data fields, please use the help section once you have logged into the ClinicalTrials.gov website. Please see appendix 7.4 for general tips and other results reporting guidance.

Steps for Results Reporting:
- Review and make any necessary changes indicated by messages below the data fields on the Edit Protocol Record screen.

- After you have completed data entry for a record you need to submit the record. Once the record has been submitted, the RGIT Administrator will be notified by email that the record is ready for review. The RGIT Administrator will check the record and either confirm that it is ready to release to the ClinicalTrials.gov team for their review or it will contact the study team to make needed changes before it can be released.

- Once the record has been released to ClinicalTrials.gov for review it may take a few weeks before their team returns with comments. You will receive an automatic email once the ClinicalTrials.gov team have completed their review. You will need to log in and address any issues highlighted and correct the record. Once you have done this you will submit the record again and it will go to the RGIT Administrator who will release it back to the ClinicalTrials.gov team. If you have not made the needed corrections, the ClinicalTirals.gov team will not allow the record to be made public. **Errors are denoted by red flags in the entry. If there are any errors the entry will not be made public. You are responsible for correcting and replying to all comments and corrections from ClinicalTrials.gov reviewers until they are satisfied with the quality of your entry.**

- Once ClinicalTrials.gov confirms that all issues have been resolved the record should be published within two working days.

Figure 1: Reviewer stages and responsibilities

5. ISRCTN

ISRCTN is a publicly accessible clinical trial registry which accepts all research studies; both prospective and retrospective registrations are accepted. It is officially recognised by the World Health Organisation (WHO) and the International Committee of Medical Journal Editors (ICMJE) as a primary clinical trials registry.

On 20th October 2021, the Health Research Authority (HRA) announced their partnership with ISRCTN registry, leading to a service which will automatically register all clinical trials of investigational medical products (CTIMPs), beginning on or after 1st January 2022. There is no charge to sponsors or trialists for automatic registration under an agreement between the HRA, Department of Health and Social Care and the ISRCTN registry. This service is only applicable to registration of CTIMPs but the HRA has stated this service will be rolled out to other types of clinical trials in the future.

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The partnership is part of the HRA's [Make it Public strategy](#) (Cited 22 December 2021) and supports the UK's commitments to the [G7 Therapeutics and Vaccines Clinical Trials Charter](#). (Cited 22 December 2021)

Studies registered on ISRCTN should have either a results publication or a basic results summary added within 12 months of the overall end date.

5.1. Registering on ISRCTN (CTIMP studies)

For CTIMPs that are automatically registered by the HRA, researchers and sponsors will not have to apply for registration separately. Registration will be free for CTIMPs using combined review, via the new part of IRAS, that are submitted on or after 1 January 2022. The HRA will not be registering any CTIMPs that are submitted prior to this date.

For studies that are automatically registered by the HRA, researchers and sponsors are not required to create an account under ISRCTN since the records are automatically created using the [data](#) submitted in your IRAS application (Cited 22 December 2021). Upon confirmation of a registration, ISRCTN will generate a unique registration number which will be passed on to the HRA and shared with the trialists and sponsors.

5.2. Registering on ISRCTN (non-CTIMP studies)

If you would like to register a non-CTIMP clinical trial on ISRCTN, please note that this will be subjected to a registration fee of *GBP 226 + tax when applicable.* Since these studies will also not be automatically registered by the HRA, you will have to create yourself an account on the ISRCTN website which will give you access to register trials on the system.

To register a new study:

- Go to [isrctn](#).com and click on "Register your study'. (Cited 22 December 2021)
- Create an account or go to the "login section".
- After login, the application has four stages: trial details, contacts, sponsors/funders, payment agreement.
- Navigate through the sections by clicking on the circles and click on "Save" to save your progress.
- Complete all the required fields and once all the sections are complete, click on "Submit".

Once your application has been received, a member of the editorial team at ISRCTN will contact you by email within 1 working day for any supporting information/clarification needed. If the study details are in line with their editorial policies and the payment has been successfully processed, the study will be assigned a registration number and the record will be immediately added to the registry.

Please be aware that a study will permanently remain on the register and cannot be deleted once it has been registered on the ISRCTN registry. If you notice that two or more ISRCTNs have been assigned to the same trial, please notify the [ISRCTN editorial team](#) immediately.

5.3. Maintaining your ISRCTN record

For CTIMPs beginning on or after 1 January 2022, entries will be made up of information submitted to IRAS via the combined review service. Any amendments in IRAS will be

automatically fed into the ISRCTN update process so the Principal Investigator and/or the sponsor will not have to update both systems.

If you would like to make any other changes to your record that is not automatically fed into the system by IRAS, please follow the instructions below:

- Go to iscrtn.com and click on "Update your record". (Cited 22 December 2021)
- This will lead to an online form where you can quote the ISRCTN number of the record you wish to update; there is no need to log in.
-
- Edit any fields in the study record that you wish to update.
- Click on "Choose files" to upload any related files e.g., study protocol document, participant information sheet.
- Click on "Submit" once you have confirmed all the changes needed.
- Alternatively, you can also contact the ISRCTN editorial team via email requesting any changes that you would like to update on your record.

A member of the editorial team at ISRCTN will then review and record the changes and contact the study contact for confirmation via email. A link to the record will also be provided to ensure that the study team is happy with the changes made. The record will usually be updated within two working days; however, this may vary depending on the size of the update.

Once a draft record has been submitted, only ISRCTN editors have administrative access to modify or update the record. Please be aware that the ISRCTN editorial team cannot remove information from a record, or overwrite previous information, and is only able to add any updated information, with a date stamp to highlight when the changes were made to the record.

For non-CTIMP studies, the editorial team at ISRCTN will send automatic prompts to the study contacts requesting an update to their record at key milestones of the study life cycle (e.g., start and end of recruitment, study completion, results overdue, etc.). However, you are strongly encouraged to update the record yourself every time your study has a key finding to report. The ISRCTN registry will update a record on any request at any time. For instance, it will be necessary to record the conclusion of a study when known, or to add summary results. It is also important to update your record to report any study amendments, such as delays to the trials, or to update the funder and sponsor details if the previous funding has run out.

If a registry record has not had either a results publication or a basic results summary added within 12 months of the overall end date of the study, the editorial team at ISRCTN will get in touch with the sponsor of the study.

5.4. **Reporting results on ISRCTN**

All study records on ISRCTN must be updated to include information about the results within 12 months of study completion.

Steps for results reporting:

- Go to isrctn.com and click on "Report your results" and complete all the required fields. (Cited 22 December 2021)

- Click on "Choose File" to upload basic results. If you have already published your study, please also provide a link to the publication on PubMed or as a DOI (Digital Object Identifier).
- The basic results should consist of four sections: Flow, Baseline Characteristics, Outcome Measures and Adverse Events.
- Once you have finished completing all the four sections, click on "Submit".

A member of the editorial team at ISRCTN will update your study record with the results and contact you by email to confirm.

If you have not published your study or are not planning to publish, you can upload only the basic results summary to your record. Please find below the checklist of items that are required to upload the basic results summary to the record:

- **Participant Flow:** A CONSORT flow diagram showing participants involved at each stage of the study (primarily enrolment, intervention allocation, follow-up and data analysis.
- **Baseline Characteristics:** A tabular summary of the baseline demographic and clinical characteristics of the participants.
- **Outcome Measures:** A tabular summary of the outcome measures listed in your ISRCTN record. If possible, it is recommended that you present the primary outcome measures separate to the secondary outcome measures, both in the tabular format.
- **Adverse Events:** A tabular summary of all the anticipated and unanticipated serious adverse events (life-threatening) and anticipated and unanticipated non-serious adverse events (non-life threatening) with a description of the adverse event and the total number of participants affected. If there were no adverse events associated with your trial, please include this statement instead: "There were no adverse events associated with this trial".

ISRCTN has provided examples of basic results summaries, which can be accessed in Appendix 7.5.

6. REFERENCES

- Health Research Authority [Research Registration and Research Project Identifiers](#) (Cited 23 June 2020)

- International Committee of Medical Journal Editors [Clinical Trial Registration](#) (Cited 23 June 2020)

- World Health Organisation [International Clinical Trials Registry Platform (ICTRP)](#) (Cited 23 June 2020)

- [EudraCT](#) (European Union Drug Regulating Authorities Clinical Trials Database) (Cited 23 June 2020)

- [ClinicalTrials.gov](#) (Cited 23 June 2020)

- [EU Trials Tracker](#) (Cited 23 June 2020)

- Health Research Authority [What data will be shared with ISRCTN Registry](#) (Cited 22

December 2021)

- Health Research Authority [Make it Public Strategy](#) (Cited 22 December 2021)

- Department of Health & Social [Care G7 Therapeutics and Vaccines Clinical Trials Charter](#) (Cited 22 December 2021)

- [isrctn.com](#) (Cited 22 December 2021)

- Cancer Research UK [Writing for a lay audience](#) (Cited 22 December 2021)

7. APPENDICES

The following appendices list the following templates associated with this SOP which can be found on the [SOP, Associated Documents & Templates page](#). (Cited 23 June 2020)

7.1.   **Reporting Results on EudraCT**
        The RGIT's results reporting template demonstrates what type of information needs to be collected in order to report results on EudraCT. This will be useful to review before beginning your study so you know the way data needs to be disaggregated. Please [email the Research Integrity Officer](#) to request the EudraCT Results Reporting Template.

7.2.   **6.2 How to Register, Become a Results User and Report Results on   EudraCT**
        The European Medicines Agency (EMA) has created a [PowerPoint presentation](#) explaining how to register, become a results user and report results on EudraCT. (Cited 23 June 2020)

7.3.   **6.3 Guidance on Reporting Results for EudraCT**
        The EMA has created an Excel spreadsheet, called the Data Dictionary, with results related data definitions which can be found [on the EMA website](#). The EMA has also developed [tutorials](#) about results reporting. (Cited 23 June 2020)

7.4.   **6.4 Reporting Results on ClinicalTrials.gov**
        The ClinicalTrials.gov website provides [definitions related to results reporting](#). (Cited 23 June 2020)

        General tips:
        - Written language for lay public
        - Brief Title – information on the participants, condition being evaluated, intervention, do not include study design terms such as double blind or randomized
        - Official Title – study title
        - Unique Protocol ID – DOCUMAS number
        - Secondary ID – EudraCT if you have registered there

Study Status:

- Anticipated – planned number
- Actual – final number
- Actual Study Completion Date is when the final participant has been examined or received an intervention for the purposes of final collection of data for the Primary Outcome Measure
- When a study is terminated, Study Status - Terminated (enrolling participants has halted prematurely and will not resume), update Primary Completion Date and Study Completion Date to reflect when data collection ended, Change Type to Actual for both dates.
- Study Status – Withdrawn (study halted prematurely, prior to enrolment of first participant)
- If the study is suspended, then it is still a requirement to specify the Primary Completion day
- Update the Verification Date at least once per year

Oversight:

- Board affiliation – official name of the organization
- The report also includes the FDAAA column which indicates if a record is a probable Applicable Clinical Trial (pACT) or an Applicable Clinical Trial (ACT) that appears to be subject to the requirements of Section 801 of the Food and Drug Amendments Act (FDAAA 801) or 42 CFR Part 11
- The FDA's website explains more about its role in ClinicalTrials.gov information (Cited 23 June 2020)

Study Description:

- No references, complete sentences
- Brief summary – study's hypothesis or purpose, 5000 characters
- Detailed Description – more technical information, 32000 characters

Study Conditions:

- Condition names should be taken from the National Library of Medicine's Medical Subject Headings (MeSH) vocabulary when possible
- Keywords – help users to find studies in database

Study Design:

- Interventional studies are those in which participants are assigned prospectively to an intervention or interventions according to a protocol to
- Evaluate the effect of the intervention(s) on biomedical or other health-related outcomes.
- In observational studies, the investigator does not assign participants to interventions, but instead observes (for example) patients who have been given interventions in the course of routine clinical care.
- Expanded Access records are limited to situations in which procedures are available for obtaining an experimental drug or device outside of a clinical trial.
- Study Phase is defined by the US FDA for trials of drug products (including biological products). Select "N/A" for trials that do not involve drugs or biological products.
- For active studies, set Enrolment Type to Anticipated and specify the target number of participants. Update the number as needed over the course of the

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study. Upon study completion, change Type to Actual and update the enrolment if necessary.
- For Bio Specimen Description list all types of bio specimens to be retained, if any.
- Some observational studies have one Group/Cohort; case control studies typically have two.

Arms/Groups/Interventions:
- Arm (or Group/Cohort) might have a mix of interventions, name should be informative and specific – don't use Arm 1, Intervention 1
- Arm Description, include the intervention name(s), dosage form, dose, frequency and duration
- Intervention = Drug, Device, Procedure, Dietary supplement
- For Intervention Name enter the generic name of a drug. Include brand names, serial numbers and code names in the Other Intervention Names list.

Outcome measures:
- Outcome Measure information should describe WHAT is to be measured and how ("assess by questionnaire, EEG"…), not why it is measured.
- Example – Number of Participants with…", "Concentration of…", "Rate of..."

- Make each Outcome Measure Title unique and descriptive, indicating the metric to be used. Examples:
    o Change in Systolic Blood Pressure
    o Area under the plasma concentration versus time curve (AUC) of [DRUG NAME]
    o Peak Plasma Concentration (Cmax) of [DRUG NAME]
- Time Frame is usually a single point in time at which a study participant is assessed for that measure, with these exceptions:
    o Change measures (e.g., "baseline and 8 weeks")
    o Time-to-Event measures (e.g., "up to 100 weeks," "from date of randomization until the date of first documented progression or date of death from any cause, whichever came first, up to 100 months")
    o Pharmacokinetic measures (e.g., "0, 1, 2, 3, 4, 6, 8, 24 hours post-dose")

Eligibility:
- For Age Limits, if there is no minimum or maximum age, select "N/A (No limit)" from the corresponding option menu.

Contacts/Locations:
- Study official – Principal Investigator

IPD Sharing Statement:
- If planning to share individual participant data (IPD), provide a brief description of the data to be shared, availability time frame and access criteria for obtaining the data. Provide a web address (URL) for more information, if applicable.

Study Document Submission:
- Each document must not have tracked changes and must include a cover page with below details:

- o Official title of the study
- o NCT number
- o Date of the document
- The PDF to Archive website can help users convert their documents (Cited 23 June 2020)
- An uploaded document can be deleted from a ClinicalTrials.gov record even after it has been made publicly available. However, previous versions of the document(s) will remain available in the ClinicalTrials.gov Archive site
- Steps:

  To upload a single document for the first time:
  - Click on the "+ New Document" button on the Document Section page.
  - Select the appropriate document type.
  - Enter the Document Date from the document cover page.
  - Click on the "Browse..." button and locate the PDF/A file for upload.
  - Click on the green "Upload" button.

  To upload multiple documents of the same type (for example, separate ICFs for parent and child):
  - Click on the "+ Advanced..." button, select document type and click the "Next" button.
  - Enter subtitles to indicate the specific contents of each document.
  - Enter the Document Date from the document cover page.
  - Click on the "Browse..." button and locate the PDF/A file for upload.
  - Click on the green "Upload" button.

  To update and replace a previously uploaded document:
  - Click on the "Update" button under the document to be updated.
  - Enter a new Document Date from the document cover page.
  - Click on the "Browse..." button to locate the updated PDF/A file to be uploaded.
  - Click on the green "Upload" button.

  To delete a study document:
  - To delete a previously submitted document, click on the "x Delete" button for that document and confirm the operation when prompted. A previously submitted study document can be deleted from a record even after being made publicly available. However, the deleted document(s) will remain accessible on ClinicalTrials.gov, in the record's History of Changes.

  Additional Help:
  - Study Results Submission (Cited 23 June 2020)
  - Adverse Events: Video Tutorial (Cited 23 June 2020)

7.5. Reporting results on ISRCTN

The ISRCTN website provides definitions related to reporting of results. (Cited 22 December 2021)

General Tips:

- Write in plain English that is easily understood by the public. ISRCTN recommends the use of the guidance developed and used by [Cancer Research UK](). (Cited 22 December 2021)
- Ensure that the public title is in the required format. It should be brief and is easily understood by the general member of the public. Please note that this is different to the scientific title, which is intended for use in ethics and grants applications.
- Ensure that all the dates are entered in an 8-digit format (DD/MM/YYYY).
- Protocol/serial number: IRAS ID for UK registered studies, in the format IRAS 123456. You can also quote your DOCUMAS number.

The ISRCTN website has also prepared a [PDF document]() containing guidance on completing the application form. (Cited 22 December 2021)

Additional Resources:

- [How to report your study results: Video]() Tutorial (Cited 22 December 2021)
- [Online form to report your]() results (Cited 22 December 2021)
- [How to request an update to your study record at the ISRCTN registry: Video Tutorial]() (Cited 22 December 2021)
- [Online form to request an update to your study record]() (Cited 22 December 2021)
- Examples of basic results summaries (Cited 22 December 2021):
  - [ISRCTN70039829]()
  - [ISRCTN52695239]()
  - [ISRCTN18436190]()