INDONESIA CLINICAL RESEARCH REGISTRY (INA-CRR) COMPLETION GUIDELINES

1. PURPOSE

The purpose of these guidelines is to provide clear instructions for the registration of clinical research in INA-CRR. INA-CRR aims to promote transparency, accountability, and accessibility of clinical research information to support evidence-based medicine and advance global health research.

2. REQUIREMENTS

2.1. Type of Research

INA-CRR cover the research in which people, or data or biological specimens from people, are studied to understand health and disease especially taken place in Indonesia. INA-CRR accepts the registration of experimental research including clinical trial, observational, and bioequivalence study.

2.2. INA-CRR Account

2.2.1. How to get INA-CRR Account

To submit your research into INA-CRR you need to create an account. This account will be used by your organization to submit all the clinical research conducted under the supervision of your organization. To get this account you may need an official letter from the head of your organization to the Head of Badan Kebijakan Pembangunan Kesehatan, Kementerian Kesehatan. The letter must be written either in Bahasa or English language. The subject should be *"a Request for INA-CRR account"* atau *"Permohonan Akun INA-CRR"*. Please indicate an assigned person who will complete the submission (submitter) process for your organization, including the name, email, and cellular phone number. Send this letter to ina-registry@kemkes.go.id or upload this letter in our website. Your account may need up to 7 working days to be processed.

2.2.2. Account substitution

INA-CRR strongly recommends substituting the account, if the previous delegated/assigned person has been changed or no longer being part of the institution. It will ensure your institution is well informed by INA-CRR for any updates on website. Please inform any substitution by official letter, including the new details (email, cellular phone number) for the newly assigned person.

2.3. Registration Timing

INA-CRR receives the registration at any-phase of research (preparation, enrolment, complete). However, we strongly encourage you to submit your registration before the enrolment of the first participant. Early registration helps to prevent selective reporting and publication bias. Submission should be done after approval of ethic (for all research) and regulatory (BPOM) (for Bioequivalence and drug trial).

3. INA-CRR DATA-SET

The data set of INA-CRR adapt the WHO Trial Registration Data. Data set must be completed in **English language**. For Clinical trial, you may complete all the points, for other studies, some information may be skipped. The details will be explained in the next page.

General Information

- Read the information section provided on the table carefully.
- Use a comma (,) to separate the answer consisted multiple points, for example to answer inclusion criteria: 1. adults age ≥18 years, 2. recently hospitalised with COVID-19, 3. not expected to be transferred within 72 hours.

No	Question	Information	Mandatory Status
1	Registration number	INA-CRR team will assign this number after approval.	
2	Date of registry approval	INA-CRR team will assign this number after approval.	
3	Registration date	Date when research was submitted to INA-CRR.	Mandatory for all types of research.
4a, b, c	Secondary identifiers	Other identifiers besides the INA-CRR Identifying Number, if any (4a). These include: • Identifiers assigned by the sponsor (record Sponsor name and Sponsor-issued trial number (e.g. protocol number)). • Other trial registration numbers issued by other Registries. • Identifiers issued by funding bodies, collaborative research groups, regulatory authorities, ethics committees/ institutional review boards, etc. All secondary identifiers will have 2 elements: an identifier for the issuing authority (4b) (e.g. clinicaltrial.gov) plus a number (4c).	Mandatory for all types of research.
5	Primary sponsor	The individual, organization, group or other legal entity which takes responsibility for initiating, managing and/or financing a study. The Primary Sponsor is responsible for ensuring that the trial is properly registered. The Primary Sponsor may or may not be the main funder.	Mandatory for all types of research.
6	Source(s) of monetary or material support	Major source(s) of monetary or material support for the trial (e.g. funding agency, foundation, company, institution).	Mandatory for all types of research.
7a, b	Secondary sponsor	If any (7a), Additional individuals, organizations, or other legal persons, that have agreed with the primary sponsor to take on responsibilities of sponsorship (7b).	If any, mandatory for all types of research.

8	Other partners	Other essential institution(s) that considered have a great contribution along the research conduct.	Only if available.
9a	Principal Investigator (PI)	Name of the PI, complete with the title(s).	Mandatory for all types of research.
9b, c, d	Principal Investigator's address	Postal address (name & number of the street, district (kecamatan), sub-district (kelurahan), city, and country. Suggest using organizational address since it will be published on website).	Mandatory for all types of research.
9e	Principal investigator's affiliation	Formal institution or organization indicates PI's professional association. It may include details such as the organization, university, research institute, company, or department.	Mandatory for all types of research.
9f	Principal Investigator's email address	Email address used by PI for regular contact.	Mandatory for all types of research.
9g	Principal investigator's phone	Phone number used by PI for regular contact. It must be accessible for INA-CRR reviewer(s). This information will not be published on website, only for review purpose, if necessary.	Mandatory for all types of research.
10a	Contact person name for public queries	Name, postal address, affiliation, email, and phone number of the contact who will respond to general queries, including information about current recruitment status. The information provided in here is functional and not personal, it is recommended to provide institutional and not personal information. By providing this information the registrant consents that the information provided can or may be published on a public website. Once provided the information cannot be redacted or anonymized.	Mandatory for all types of research.
10b	Address for public queries		Mandatory for all types of research.
10c	City		Mandatory for all types of research.
10d	Country		Mandatory for all types of research.
10e	ZIP		Mandatory for all types of research.
10f	Affiliation for public queries		Mandatory for all types of research.
10g	Email address for public queries		Mandatory for all types of research.
10h	Phone number for public queries		Mandatory for all types of research.
11a	Name of Contact for scientific queries	Name, postal address, email address, telephone number, and affiliation of the person to contact for scientific queries about the trial (e.g., principal investigator, medical director employed by the sponsor). For a multi-centre study, enter the contact information for the lead Principal Investigator or overall scientific director. The information provided in here is functional and not personal, it is recommended to provide institutional and not personal information. By providing this information the registrant consents that the information provided can or may be published on a public website. Once provided the information cannot be redacted or anonymized.	Mandatory for all types of research.
11b	Address for scientific queries		Mandatory for all types of research.
11c	City		Mandatory for all types of research.
11d	Country		Mandatory for all types of research.
11e	ZIP		Mandatory for all types of research.
11f	Affiliation of scientific queries contact		Mandatory for all types of research.
11g	Email address for scientific queries		Mandatory for all types of research.
11h	Phone number for scientific queries		Mandatory for all types of research.

12a	Scientific study title	Scientific title of the study as it appears in the protocol submitted for funding and ethical review. Include trial acronym if available.	Mandatory for all types of research.
12b	Acronym of scientific study title		Only if available.
12c	Public (popular study title)	Title intended for the lay public in easily understood language. Include trial acronyms if available. If no public title is available, write the scientific title.	Mandatory for all types of research.
12d	Acronym of public title		Only if available.
13a	Ethical Approval number	Mention the number of Ethical Approval that valid for this study. It may include Date of approval, Name and contact details of ethics committee(s) (phone, email, and office address).	Mandatory for all types of research.
13b	Name of Ethics committee		Mandatory for all types of research.
13c	Date of Ethic approval		Mandatory for all types of research.
13d	Contact details of Ethic Committee		Mandatory for all types of research.
14	Material Transfer Agreement number (MTA)	Mention the status of Material Transfer Agreement (MTA). - Not applicable : for study need no MTA approval. - MTA number : for study need MTA approval, and has been approved, write the MTA number. - Waiting for approval : for study need MTA approval, and still waiting for the approval.	Mandatory for all types of research.
15	Number of Persetujuan Pelaksanaan Uji Klinik (PPUK)/Persetujuan Protokol Uji BE (PPUB).	Mention the status of PPUK/PPUB - Not applicable : for study other than bioequivalence or drug trial. - PPUK/PPUB number : for study bioequivalence or drug trial.	Mandatory for all types of research.
16a	Countries of recruitment	The countries from which participants will be, are intended to be, or have been recruited.	Mandatory for all types of research.
16b	Study sites in Indonesia	The study sites from which participants will be, are intended to be, or have been recruited across indonesia. For study outside Indonesia complete with “Not Applicable”.	Mandatory for all types of research.

17a	Primary health condition(s) or problem(s) studied (e.g., depression, breast cancer, medication error)	Primary health condition(s) or problem(s) studied (e.g., depression, breast cancer, medication error). If the study is conducted in healthy human volunteers belonging to the target population of the intervention (e.g. preventive or screening interventions), enter the particular health condition(s) or problem(s) being prevented. If the study is conducted in healthy human volunteers not belonging to the target population (e.g., a preliminary safety study), an appropriate keyword will be defined for users to select.	Mandatory for all types of research.
17b	Purpose of the study	Please choose one of the suitable answers for study purpose - Treatment - Prevention - Diagnostic - Supportive care - Screening - Health services research - Basic science - Other, mention the purpose _____	Mandatory for all types of research.
18a	Study type	Please choose one of the suitable answers for study type - Observational - Interventional : Bioequivalence study, Clinical trial, or Interventional, other than clinical trial.	Mandatory for all types of research.
18b	Study phase	Please choose one of the suitable answers for study phase - Phase 0 (exploratory trials) - Phase 1 - Phase 1-2 - Phase 2 - Phase 2-3 - Phase 3 - Phase 4	Mandatory for clinical trial.
18c	Method of allocation	Please choose one of the suitable answers for method of allocation (process by which participants are assigned to different treatment groups or interventions) - Not applicable (single arm study) - Non-randomized allocation - Randomized controlled trial	Mandatory for clinical trial.

18d	Description of the allocation concealment mechanism and sequence generation	The allocation concealment mechanism is a process implemented in clinical trials to ensure that the treatment assignments are concealed from those involved in the trial until the moment of randomization. Sequence generation refers to the process of generating the random allocation sequence used to assign participants to different treatment groups in a clinical trial. It is an essential step in the randomization process and helps ensure that treatment assignments are unbiased and independent of any factors that could influence the results. The sequence generation process typically involves using a randomization algorithm or method to assign participants to different treatment groups. Common methods include simple randomization, stratified randomization, blocked randomization.	Mandatory for clinical trial, randomized controlled trial.
18e	Masking	Registries may collect data on who is masked (the subjects, therapist or clinician, assessor, or data analyst) and/or use the terms double blind or single blind.	Mandatory for experimental/interventional study.
18f	Study intervention	For study intervention, describe other intervention details as applicable (dose, duration, mode of administration, etc.). Enter the specific name of the **intervention(s)**. Use the International Non-Proprietary Name if possible (not brand/trade names). For an unregistered drug, the generic name, chemical name, or company serial number is acceptable. If the intervention consists of several separate treatments, list them all in one line separated by commas (e.g., "low-fat diet, exercise").	Mandatory for experimental/interventional study.
18g	Control intervention (control arm)	The control intervention(s) is/are the interventions against which the study intervention is evaluated (e.g., placebo, no treatment, active control). If an active control is used, be sure to enter in the name(s) of that intervention or enter "placebo" or "no treatment" as applicable. For control intervention, describe other intervention details as applicable (dose, duration, mode of administration, etc)	Mandatory for experimental/interventional study.
18h	Intervention assignment	Please choose one of the suitable answers for Intervention Assignment - Single arm - Parallel - Crossover - Factorial - other	Mandatory for experimental/interventional study.

19a, b, c, d	Inclusion criteria	Mention the inclusion and exclusion criteria for the study, including age and sex on several points regarding inclusion criteria. Use a comma (,) between criteria.	Mandatory for all types of research.
19e	Exclusion criteria		Mandatory for all types of research.
20a	Type of enrolment	Please choose the status of enrollment at the time of your submission, anticipated or actual date of enrollment of the first participant.	Mandatory for all types of research.
20b	Date of first enrolment		Mandatory for all types of research.
21a	Targeted sample size	Provide the number of participants that this trial plans to enroll in Indonesia (for study in Indonesia).	Mandatory for all types of research.
21b	Number of enrolled participants	Provide the number of participants that the trial has enrolled (for study in Indonesia).	Mandatory for all types of research.
22a	Name of primary outcome	The data required for each outcome is: • Outcome name • Timepoints • Measure All of the data for a primary outcome should be provided to the WHO Search Portal in a single line.	Mandatory for all types of research.
22b	Metric/method of measurement		Mandatory for all types of research.
22c	Timepoint(s) of measurement		Mandatory for all types of research.
23	Secondary outcome		Mandatory for all types of research.
24	Recruitment status	Please mention the status at recruitment at submission - Initial : participants are not yet recruited or enrolled at any site. - Recruiting : participants are currently being recruited and enrolled. - Complete : participants are no longer being recruited or enrolled. - Suspended : there is a temporary halt in recruitment and enrolment.	Mandatory for all types of research.
25	Date of study completion (last participant, last visit)	The date on which the final data for a clinical study were collected (commonly referred to as, "last subject, last visit").	Mandatory for all types of research, with completion status “Complete”.
26a	Brief summary of study results	Please write a summary of important findings on your study.	Mandatory for all types of research.
26b	Date of results summaries	Date of posting result summaries.	Mandatory for all types of research.
26c	Participant flow	Information to document the progress and numbers of research participants through each stage of a study in a flow diagram or tabular format.	Mandatory for experimental/interventional study.
26d	Baseline characteristic	Data collected at the beginning of a clinical study for all participants and for each arm or comparison group. These data include demographics, such as age and sex, and study-specific measures.	Mandatory for experimental/interventional study.

26e	Adverse events	An unfavorable change in the health of a participant, including abnormal laboratory findings, and all serious adverse events and deaths that happen during a clinical study or within a certain time period after the study has ended. This change may or may not be caused by the intervention being studied.	Mandatory for experimental/interventional study.
26f	Outcome measures	A table of data for each primary and secondary outcome measure and their respective measurement of precision (eg a 95% confidence interval) by arm (that is, initial assignment of participants to arms or groups) or comparison group (that is, analysis groups), including the result(s) of scientifically appropriate statistical analyses that were performed on the outcome measure data, if any.	Mandatory for experimental/interventional study.
27a	Publication for submitted study	Mention the title for study journal publication.	Mandatory for all types of research.
27b	Date of the first journal publication of results	Mention the date of first published journal publication for your study.	Mandatory for all types of research.
28	URL hyperlink(s) related to results and publications	Mention URL for study journal publication.	Mandatory for all types of research.
29	URL link to protocol file(s) with version and date	Mention URL for protocol with version and date, please make sure that the link is accessible for the reviewers. Create a specific folder that is accessible for the reviewer(s). This folder should be completed by updated study protocol, IRB/ethical approval, PPUB/PPUK (if any).	Mandatory for all types of research.
30a	IPD sharing statement (Statement regarding the intended sharing of deidentified individual clinical trial participant-level data (IPD)	Statement regarding the intended sharing of deidentified individual clinical trial participant-level data (IPD). Should indicate whether IPD will be shared, what IPD will be shared, when, by what mechanism, with whom and for what types of analyses. 1. Plan to share IPD (Yes, No, Undecided) 2. Plan description	Mandatory for all types of research.
30b	Plan for IPD sharing (what IPD will be shared, when, by what mechanism, with whom, and for what types of analyses)		Mandatory for all types of research.
31	Other important information	Any information related to your study that should be informed to reviewer, for example for multi country study, mention the number of enrolled participants in all countries.	Optional

4. Start your registration

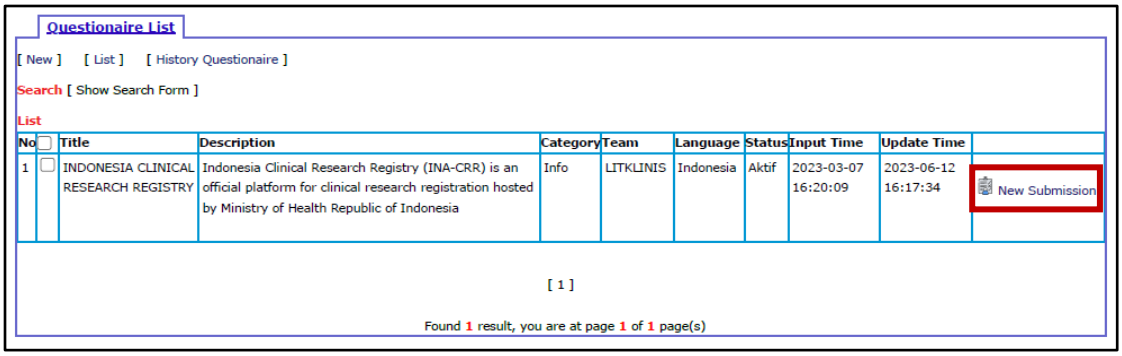
If all the information require on the data set has been completed, you may start the process of clinical research registration on INA-CRR website.

a. Ensure you have a stable internet connection and a web browser installed on your computer or mobile device.

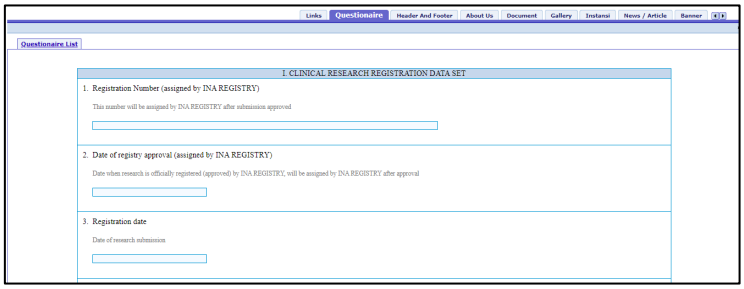
b. Login to the INA-CRR website with the user and password.

c. Once you login, you will see this view on your webpage, click the icon "**Questionaire**".

d. After clicking Questionaire icon you will navigate to INA-CRR form, click **"New Submission"** icon.



e. You will then navigate to **Clinical Research Registration Data Set**.



f. Read the instructions in the form or guidelines. Take a moment to read and understand them before proceeding.

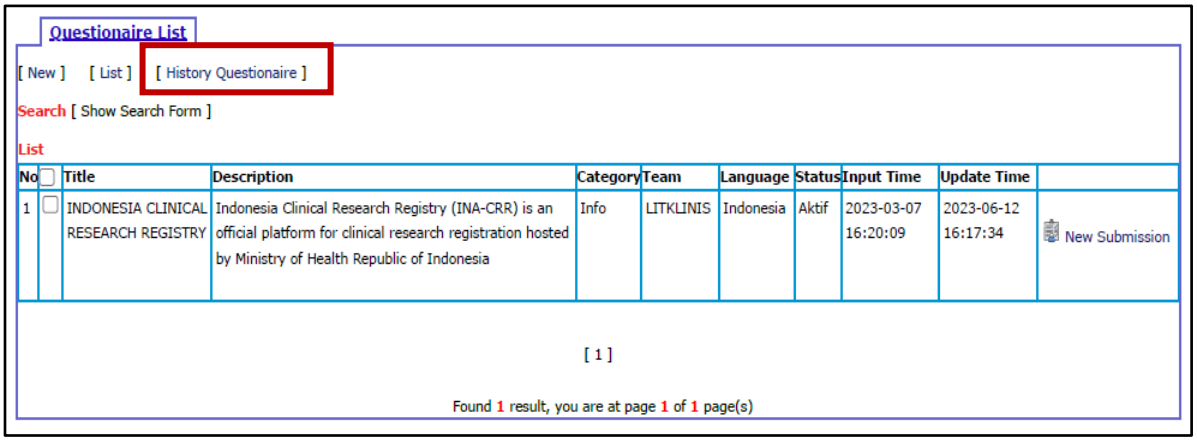
g. Review your responses: Once you have answered all the questions, take a moment to review your responses to ensure they are accurate and complete.

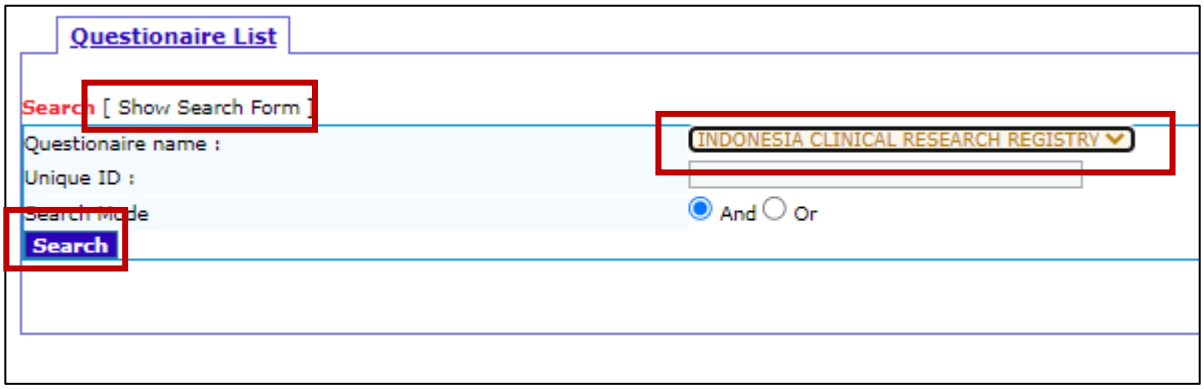
h. Submit the form: To submit the form, click on the **"Save"** button usually located at the bottom of the form. Some forms may require you to click on a "Next" button to proceed to the next section before you can submit.

i. Confirmation message: After submitting the form, you may see a confirmation message indicating that your responses have been successfully recorded.

j. INA-CRR team will review your submission and assign the registration number after approval.

k. You can view your submission by clicking the icons **"History Questionaire" → "Show Search Form" → select "INDONESIA CLINICAL RESEARCH REGISTRY" → "Search"**





l. Select the registration you want to show by clicking icon **"View Answer"** in the selected point.

5. Data/Information correction or revision

Before starting the data set completion, the submitter needs to ensure that all information in the data set has been provided accurately and comprehensively. Inaccurate and Incomprehensive data may lengthen the approval process due to the back-and-forth process between the reviewer and submitter. To make corrections to the information that has been registered, you must contact the INA-CRR team via email ina-registry@kemkes.go.id using the subject **"Data Correction"**. Please state the registry number (if any), date of submission, scientific title, information to be corrected on INA-CRR Data Clarification Form (INA-CRR DCF) (before and after correction). State the reason why the correction is made. INA-CRR team will review your request.