Required items and definitions for registering at TCTR

Please note: The information requested for the data items is based on the definitions and set requirements for trial registration of the International Committee of Medical Journal Editors (ICMJE) and World Health Organization (WHO) trial registration minimum data set.

Mandatory data items for trial registration with the TCTR are marked with an **ASTERISK**.

Data Item	Definitions	Requested Information
Section: TITLE		
1. **Sponsor ID/ IRB ID/EC ID ***	It is the unique identification number that assigned to the protocol by the sponsoring organization. If there was none, please invent it so that it can be used by the ClinicalTrials.in.th as the reference for further actions as needed. It must be one and only one number for each protocol.	[Free text] Limit to 30 characters Examples: NRTC-12345, TH0899, CHC 021/2010
2. **Study Identification Number ***	This is the identification number assigned to the protocol by the primary registration site where this protocol had been first registered. This is for clinical studies conducted in South East Asia to be listed in Thai Clinical Trials Registry (TCTR), no matter wherever they had already been registered. For the protocol that first register at TCTR, the Primary (Site) ID will be assigned to the protocol automatically.	[Please select] ☐ TCTR is the primary registration site, the ID for this protocol is. ☐ TCTR is NOT the primary registration site, please specify below.
3. **Date of Registration in Primary Registry ***	This is the registered date. It is based on the date that was first registered at the Primary registration site. For the protocol that registers at Thai Clinical Trials Registry (TCTR) as the first site, the date will be populated after information of the current protocol has been approved and released. Note that the protocol will be released to public after you have entered all required data, clicked [Submitted for Approval], and the Committee of the TCTR approved it.	To be populated after the trial being released
4. **Secondary IDs ***	Other identifiers besides the Trial Identifying Number allocated by the Primary Registry, if any. These should include: • The Universal Trial Number (UTN) • Identifiers assigned by the sponsor (record sponsor name and sponsor-issued trial number (e.g., protocol number)). • Other trial registration numbers • Identifiers issued by funding bodies, collaborative research groups, regulatory authorities, ethics committees / institutional review boards, etc.	[Free text] [Please choose and insert text for ID Type where appropriate] ID Type: ☐ The Universal Trial Number (UTN) ☐ US NIH Grant Number ☐ Other Grant/Funding Number; Grantor or Funder: ☐ Registry Identifier; Registry:

Data Item	Definitions	Requested Information
	All secondary identifiers will have 2 elements: an identifier for the issuing authority (eg CTN, ISRCTN, ACTRN) plus a number. There is no limit to the number of secondary identifiers that can be provided.	☐ EudraCT Number (European Union Drug Regulatory Authorities Clinical Trial System) ☐ Other Identifier; Issuing Organization: [ ] Add
5. Public Title	Short and simple protocol title intended for lay public	[Free text] Limit to 300 Characters Example: Effect of inhale corticosteriod on asthma control in Thailand
6. Acronym	This is abbreviations that are formed using the initial components in the protocol title that used to identify this study. This is an optional. If entered, the acronym will be automatically displayed in parentheses following the brief title.	[Free text] Limit to 20 Characters Example: **Brief Title:** Asthma in Young Adults **Acronym:** AYA **Displayed on TCTR as**: Asthma in Young Adults (AYA)
7. **Scientific Title ***	Title of the protocol provided by the study principal investigator or sponsor. It should be updated later to correspond the one that was approved by the IRB/EC.	[Free text] **Limit** to 500 characters **Example :** Effect of Green Tea on Body Weight : A Double-blinded Randomized Controlled Trial.
8. **Study Type ***	Please select type of the study from the following list • **Interventional**: studies in human beings in which individuals are assigned by an investigator based on a protocol to receive specific interventions. Subjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed. • **Observational**: studies in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study.	[Please select one] ☐ Interventional ☐ Observational
Section:		

Data Item	Definitions	Requested Information
OVERSIGHT		
9. Board Approval	This indicates the status of the Institutional Review Board or the Ethics Committee (IRB/EC) approval. Please select one from the following list: • Request not yet submitted: review board approval is required but has not yet been requested • Submitted, pending: review board approval has been requested but not yet granted • Submitted, approved: review board approval has been requested and obtained • Submitted, exempt: review board has granted an exemption in response to the approval request • Submitted, denied: review board has denied the approval request • Submission not required: the study does not require human subjects review	[Please select one from the drop-down list] Remark: For the study with the status "Submitted, approved", the [Approval Number] should be specified in the adjacent text box. Board Approval Number is the number assigned by the IRB/EC upon approval of the protocol. May be omitted if status is anything other than approved. If the IRB/EC does not assign numbers, [please enter the date of approval in dd/mm/yyyy format].
10. Board Name	Provide full name of the approving Institutional Review Board or Ethics Committee (IRB/EC).	[Free text] Please specify only the main IRB/EC if the study involve multiple boards. **Example** : Khon Kaen University Ethics Committee of Human Research
11. Board Affiliation	Provide the official name of organizational affiliation of the approving Institutional Review Board or Ethics Committee (IRB/EC).	[Free text] Please specify only for the main review board. **Example** : **Board Name**: Khon Kaen University Ethics Committee of Human Research **Board Affiliation**: Khon Kaen University, Thailand
12. Board Contact	Provide the contact information of the approving Institutional Review Board or Ethics Committee (IRB/EC).	[Free text] Please specify only for the contact address of the main review board. Business Phone : Extension : Business Email : Business Address : **Example** : **Board Name**: Khon Kaen University Ethics Committee of Human Research

Data Item	Definitions	Requested Information
		Board Affiliation: Khon Kaen University, Thailand **Board Contact**: **Business Phone** : +66+43+366616 **Extension** : - **Business Email** : eckku@kku.acth **Business Address** : Khon Kaen University Ethics Committee of Human Research 123 Friendship Road Khon Kaen University, 40002 Thailand
13. Data Monitoring Committee	Indicate whether a data monitoring committee has been appointed for this study. The data monitoring committee (board) is a group of independent scientists who are appointed to monitor the safety and scientific integrity of a human research intervention, and to make recommendations to the sponsor regarding the stopping of the trial for efficacy, for harms or for futility. The composition of the committee is dependent upon the scientific skills and knowledge required for monitoring the particular study.	[Please select either YES or NO]
Section: SPONSOR		
14. Source(s) of Monetary or Material Support	Name of primary organization that oversees implementation of study and is responsible for data analysis	[Free text] **Limit** to 200 characters **Example** : Thailand Center of Excellence for Life Sciences (TCELS)
15. Study 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 ensuring that the trial is properly registered. The Primary Sponsor may or may not be the main funder.	[Free text]

Data Item	Definitions	Requested Information
16. Study Secondary Sponsor	This is to specify additional individuals, organizations or other legal persons that have agreed with the primary sponsor to take on responsibilities of sponsorship. A secondary sponsor may have agreed: • to take on all the responsibilities of sponsorship jointly with the primary sponsor; or • to form a group with the primary sponsor in which the responsibilities of sponsorship are allocated among the members of the group; or • to act as the sponsor's legal representative in relation to some or all of the trial sites; or • to take responsibility for the accuracy of trial registration information submitted.	[Free text] **Limit** to 200 characters **Example** : National Research Council of Thailand (NRCT) Health System Research Institute (HSRI)
17. Responsible Party	Responsible party means the sponsor of the clinical trial or the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements for the submission of clinical trial information. Please provide the following information for the designated responsible party: • **Name/Official Title** - for either the principal investigator or sponsor contact • **Organization** - the sponsor or the principal investigator's organizational affiliation • **Contact Information** - required for internal administrative use only; not revealed to public] provide telephone number and/or email address	[Free text] Name/Official Title : Organization : Phone : Extension : Email :
Section: SUMMARY		
18. Brief Summary	Provide short description of the protocol intended for the lay public. Please include brief statements of the study research	[Free text] Limit to 5,000 Characters **Example** :Effects of inhaled corticosteroids (ICS) on

Data Item	Definitions	Requested Information
	objective(s) and the study design.	asthma control in real clinical practice are scarce. We will investigate if ICS alone are enough for asthma control in real practice.
19. Detailed Description	Extended description of the protocol, including more technical information (as compared to the Brief Summary) if desired. Please do not include the entire protocol.	[Free text] Limit to 40,000 Characters **Example**: Inhaled corticosteroids (ICS) are currently the main treatment of persistent asthma. Guidelines recommend using alone and in combination with other controllers e.g. long-acting beta2-agonist (LABA), theophylline and anti-leukotriene. We will investigate if ICS alone are enough for asthma control in real practice. This study aims to determine percentage of patients who achieved asthma control after receiving ICS for ≥ 3 months in clinical practice. This is a hospital-based cross-sectional, multi-center study. Patients will be consecutively enrolled if they were ≥ 12 years old, had persistent asthma and receiving any ICS, but no LABA, for ≥ 3 months.
Section: STATUS		
20. Overall Recruitment Status	Overall recruitment activity for the study. This requires to be updated throughout the course of the study. Please select one from the following list: • **Not yet recruiting**: participants are not yet being recruited • **Recruiting**: participants are currently being recruited • **Enrolling by invitation**: participants are being (or will be) selected from a predetermined population • **Active, not recruiting**: study is ongoing (i.e., patients are being treated or examined), but participants are not currently being recruited or enrolled • **Completed**: the study has concluded normally; participants are no longer being examined or treated (i.e., last patient's last visit has occurred) • **Suspended**: recruiting or enrolling participants has halted prematurely but potentially will resume • **Terminated**: recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated • **Withdrawn**: study halted prematurely, prior to enrollment of first participant	[Please select from the drop-down list]

Data Item	Definitions	Requested Information
21. Why Study Stopped	For suspended, terminated or withdrawn studies, please provide a brief explanation of why the study has been halted or terminated.	[Free text] Limit to 200 characters
22. **Study Start Date (First Enrollment) ***	Provide the begin date of enrolment of the study as stated in the protocol. Please also indicate that it is "Anticipated" or "Actual" from the adjacent menu. For active studies, please select "Anticipated" and specify the expected completion date. Please update the date as needed over the course of the study. Upon study completion, please change it to "Actual" and update the date if necessary.	[Please enter the date in dd/mm/yyyy format] [Choose either anticipated or Actual]
23. Primary Completion Date	Provide date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated. Please also indicate that it is "Anticipated" or "Actual" from the adjacent menu. For active studies, please select "Anticipated" and specify the expected completion date. Please update the date as needed over the course of the study. Upon study completion, please change it to "Actual" and update the date if necessary.	[Please enter the date in mm/dd/yyyy format] [Choose either anticipated or Actual]
24. Study Completion Date	Provide the final date on which data was (or is expected to be) collected. Please also indicate that it is "Anticipated" or "Actual" from the adjacent menu. For active studies, please select "Anticipated" and specify the expected completion date. Please update the date as needed over the course of the study. Upon study completion, please change it to "Actual" and update the date if necessary.	[Please enter the date in mm/dd/yyyy format] [Choose either anticipated or Actual]
Section: DESIGN		
25. **Primary Outcome ***	**Primary outcome** (or endpoint or response variable or dependent variable) is the main effect of experimental variables in a study, or for observational studies, the patterns of diseases or traits or associations with exposures, risk factors or treatment. **Time frame** is the time point(s) at which	[Please fill the form below] **Outcome name :** **Metric/method of measurement :** **Time point :** **Safety Issue? :** No

Data Item	Definitions	Requested Information
	outcome measure is assessed. **Safety issue** is to specify whether or not this outcome measure assessing a safety issue. Please select: Yes/No	**Example** : **Outcome**: Readmission to the hospital **Time Frame**: one year **Safety Issue?**: No
26. **Secondary Outcome ***	Provide other key variables that will be used to evaluate effect of the intervention(s) or, for observational studies, that are a focus of the study. Usually these correspond to the secondary aims of the study. Please specify Outcome measure, Time Frame, and Safety Issue as described above.	[Please fill the form below] **Outcome name :** **Metric/method of measurement :** **Time point :** **Safety Issue? :** No **Example** : **Outcome Measure**: Number of accident falls **Time Frame**: one year **Safety Issue?**: No
27. **Primary Purpose ***	Primary Purpose is the reason for the protocol. Please select one from the following list: • **Treatment**: protocol designed to evaluate one or more interventions for treating a disease, syndrome or condition • **Prevention**: protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition • **Diagnostic**: protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition • **Supportive Care**: protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects or mitigate against a decline in the subject's health or function. In general, supportive care interventions are not intended to cure a disease. • **Screening**: protocol designed to assess or examine methods of identifying a condition (or risk factors for a condition) in people who are not yet known to have the condition (or risk factor). • **Health Services Research**: protocol designed to evaluate the delivery, processes, management, organization or financing of health	[Please choose from a drop-down list]

Data Item	Definitions	Requested Information
	care. • **Basic Science**: protocol designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention. • **Other**: describe in Detailed Description.	
28. **Study Phase ***	Phase of investigation, as defined by the US FDA for trials involving investigational new drugs. Please select one from the following list: • **N/A** : for trials without phases • **Phase 0** : exploratory trials, involving very limited human exposure, with no therapeutic or diagnostic intent (e.g., screening studies, microdose studies). See FDA guidance on exploratory IND studies for more information. • **Phase 1** : includes initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients • **Phase 1/Phase 2:** for trials that are combinations of phase 1 and phase 2 • **Phase 2**: includes controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks • **Phase 2/Phase 3**: for trials that are a combination of phase 2 and phase 3 • **Phase 3**: includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labelling • **Phase 4**: studies of FDA-approved drugs to delineate additional information including the drug's risks, benefits, and optimal use	[Please choose from a drop-down list]
29. **Intervention Model ***	Intervention Model refers to intervention assignments in experimental studies.	[Please choose from a drop-down list]

Data Item	Definitions	Requested Information
	Please select one from the following list: • **Single Group**: single arm study • **Parallel**: participants are assigned to one of two or more groups in parallel for the duration of the study • **Cross-over**: participants receive one of two alternative interventions during the initial phase of the study and receive the other intervention during the second phase of the study • **Factorial**: two or more interventions, each alone and in combination, are evaluated in parallel against a control group	
30. Number of Arms/Study groups	Specify number of intervention groups/study groups	[Insert Number of intervention groups/study groups] Example: enter 1 for single-arm study
31. Masking	Masking is knowledge of intervention assignments. Open: no masking is used. All involved know the identity of the intervention assignment. Masked roles include: • **Open label:** no masking is used. All involved know the identity of the intervention assignment. • **Single Blind**: one party, either the investigator or participant, is unaware of the intervention assignment; also called single-masked study. • **Double Blind**: two or more parties are unaware of the intervention assignment	[Please choose from a drop-down list] **Masked Roles :** ☐ Subject ☐ Caregiver ☐ Investigator ☐ Outcomes Assessor Remark: If Single Blind or Double Blind is selected, [Check the role(s) that are to be masked]: Subject, Caregiver, Investigator or Outcomes Assessor.]
32. Allocation	Provide methods of assignment of study subject to intervention groups. Please select one from the following list: • **N/A**: single arm study • **Randomized Controlled Trial**: participants are assigned to intervention groups by chance • **Nonrandomized Trial**: participants are expressly assigned to intervention groups through a non-random method, such as physician choice	[Please choose from a drop-down list]

Data Item	Definitions	Requested Information
33. Control		[Please choose from a drop-down list]
34. Study Endpoint Classification	Study Endpoint Classification refers to type of primary outcome or endpoint that the protocol is designed to evaluate. Please select one from the following list. • **N/A**: not applicable • **Safety**: show if the drug is safe under conditions of proposed use • **Efficacy**: measure of an intervention's influence on a disease or health condition • **Safety/Efficacy**: combination of safety and efficacy as defined above • **Bio-equivalence**: scientific basis for comparing generic and brand name drugs • **Bio-availability**: rate and extent to which a drug is absorbed or otherwise available to the treatment site in the body • **Pharmacokinetics**: the action of a drug in the body over a period of time including the process of absorption, distribution and localization in tissue, biotransformation, and excretion of the compound • **Pharmacodynamics**: action of drugs in living systems • **Pharmacokinetics/dynamics**: combination of both defined above	[Please choose from a drop-down list]
35. **Enrollment ***	Specify number of subjects in the trial. A "Type" menu is also included, with options Anticipated and Actual. For active studies, set Type to Anticipated and specify the expected enrollment, updating the number as needed over the course of the study. Upon study completion, change Type to Actual and update the enrollment if necessary.	[Insert number of subjects] [Choose either anticipated or Actual]
Section: INTERVENTIONS/ STUDY GROUPS		
36. **Intervention Name ***	Specify the short name used to identify the arm. • For drugs use generic name; for other types of interventions provide a brief descriptive name. • For investigational new drugs that do not yet have a generic name, a chemical name, company code or serial number may be used on a	[Free text] Limit to 62 characters

Data Item	Definitions	Requested Information
	temporary basis. As soon as the generic name has been established, update the associated registered records accordingly. • For non-drug intervention types, provide an intervention name with sufficient detail so that it can be distinguished from other similar interventions.	
37. **Intervention Type ***	Please select one from the following list: • Experimental • Active Comparator • Placebo Comparator • Sham Comparator • No intervention • Other	[Please choose from a drop-down list]
38. **Intervention Classification ***	Please select one from the following list: • Drug (including placebo) • Device (including sham) • Biological/Vaccine • Procedure/Surgery • Radiation • Behavioral (e.g., Psychotherapy, Lifestyle Counseling) • Genetic (including gene transfer, stem cell and recombinant DNA) • Dietary Supplement (e.g., vitamins, minerals) • No intervention • Other	[Please choose from a drop-down list]
39. **Intervention Descriptions ***	Provide key details of the intervention. Must be sufficiently detailed to distinguish between arms of a study (e.g., comparison of different dosages of drug) and/or among similar interventions (e.g., comparison of multiple implantable cardiac defibrillators). For example, interventions involving drugs may include dosage form, dosage, frequency and duration	[Free text] Limit to 1000 characters **Example**: 50 mg/m2, IV (in the vein) on day 5 of each 28 day cycle. Number of Cycles: until progression or unacceptable toxicity develops.
Section: CONDITIONS		
40. **Health Condition (s) or Problem(s) Studied ***	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	[Free text] Enter only condition or focus (no numbers, dashes, bullets, etc.), one per line **Example**: Hip Fractures
41. Keywords	Specify words or phrases that best describe the protocol. Keywords help users	[Free text]

Data Item	Definitions	Requested Information
	find studies in the database. Use NLM's Medical Subject Heading (MeSH) controlled vocabulary terms where appropriate. Be as specific and precise as possible. Avoid acronyms and abbreviations.	Enter only Keywords (no numbers, dashes, bullets, etc.), one per line. **Example**: Hip fracture readmission to the hospital elderly falls
Section: ELIGIBILITY		
42. **Inclusion Criteria ***	Inclusion criteria for participant selection. The preferred format includes lists of inclusion criteria as shown below. Pleas avoid duplication with other information in the following items such as age limit and gender.	[Free text] Limit to 15,000 characters **Example**: Fist time in life being hospitalized due to hip fracture due to accident fall
43. **Gender ***	Physical gender of individuals who may participate in the protocol. Please select one from the following list. • **Both**: both female and male participants are being studied • **Female**: only female participants are being studied • **Male**: only male participants are being studied:	[Please select from a drop-down list]
44. **Age Limit ***	• **Minimum** age of participants: Provide a number and select a unit of time (years, months, weeks, days, hours or minutes). • **Maximum** age of participants: Provide a number and a unit of time (years, months, weeks, days, hours or minutes).	Minimum : [ ] Years Maximum : [ ] Years Select "N/A (No limit)" if no minimum age is indicated.
45. **Exclusion Criteria ***	Exclusion criteria for participant selection. The preferred format includes lists of exclusion criteria as shown below. Pleas avoid duplication with other information in the following items such as age limit and gender.	[Free text] Limit to 15,000 characters **Example**: 1. Presentation of any physical disability 2. Participation in a clinical study (excluding non-interventional study or registry) during the last 3 months
46. Accept Healthy Volunteers	Indicate if persons who have not had the condition(s) being studied or otherwise related conditions or symptoms, as specified in the eligibility requirements, may participate in the study. Select Yes/No.	[Please select either YES or NO]
Section: LOCATION		

Data Item	Definitions	Requested Information
47. **Central Contact***	Person providing centralized, coordinated recruitment information for the entire study.	[Free text] • First Name • Middle Initial • Last Name • Degree • Phone: office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code. • Ext: phone extension, if needed • Email: electronic mail address of the facility contact person
48. **Central Contact Backup ***	Person to contact if Central contact person is not available (i.e., a second contact person).	[Free text] • First Name • Middle Initial • Last Name • Degree • Phone: office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code. • Ext: phone extension, if needed • Email: electronic mail address of the facility contact person
49. **Facility ***	Facility is the full name of the organization where the protocol is being conducted. Under each of the study center, investigators name can be added more than one.	[Free text] **Example** : • **Site Name**: Department of Ophthalmology, Faculty of Medicine, Khon Kaen University • **City** : Muang • **State/Province** : Khon Kaen **Postal Code** : 40002 • **Country** : Thailand
50. **Recruitment Status ***	Protocol accrual activity at a facility. Please select one from the following list: • **Not yet recruiting**: participants are not yet being recruited • **Recruiting**: participants are currently being recruited • **Enrolling by invitation**: participants are being (or will be) selected from a predetermined population • **Active, not recruiting**: study is ongoing (i.e., patients are being treated or examined), but participants are not currently being recruited or enrolled • **Completed**: the study has concluded normally; participants are no longer being examined or treated (i.e., last patient's last visit	[Please select from a drop-down list]

Data Item	Definitions	Requested Information
	has occurred) • **Suspended**: recruiting or enrolling participants has halted prematurely but potentially will resume • **Terminated**: recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated • **Withdrawn**: study halted prematurely, prior to enrollment of first participant	
51. **Facility Contact***	Contact information of the Contact person at the specified study center.	[Free text] • First Name • Middle Initial • Last Name • Degree • Phone: office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code. • Ext: phone extension, if needed • Email: electronic mail address of the facility contact person
52. **Facility Contact Backup***	Contact information of the Backup contact person at the specified study center. It is the person to contact if Facility Contact is not available (i.e., a second contact person).	[Free text] • First Name • Middle Initial • Last Name • Degree • Phone: office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code. • Ext: phone extension, if needed • Email: electronic mail address of the facility contact person
53. **Investigator Name***	Specify information of the investigator in this study site.	[Free text] • First Name • Middle Initial • Last Name • Degrees

Data Item	Definitions	Requested Information
54. **Role***	Select one (Site Principal Investigator or Site Sub-Investigator)	[Please select one]
Section: CITATIONS		
55. MEDLINE Identifier	This refers to the unique PubMed Identifier (PMID) for the citation in MEDLINE.	[Free text] Example: PMID: 21747329
56. Citation	Citation is the bibliographic reference in NLM's MEDLINE format	[Free text] Limit to 2,000 characters **Example** : Ploenchan Chetchotisakd, Wipada Chaowagul, Piroon Mootsikapun, Duangkaew Budhsarawong, Bandit Thinkhamrop. Maintenance therapy of melioidosis with ciprofloxacin plus azithromycin compared with cotrimoxazole plus doxycycline. Am. J. Trop. Med. Hyg. 2001;64(1,2): 24-27.
57. Results Reference	Indicate if the reference provided reports on results from this clinical research study.	[Please select either YES or NO]
Section: LINKS		
58. Add new URL	A Web site directly relevant to the protocol may be entered, if desired. Do not include sites whose primary goal is to advertise or sell commercial products or services. Links to educational, research, government, and other non-profit Web pages are acceptable. All submitted links are subject to review by ClinicalTrials.in.th.	[http://...] Limit to 254 characters **Example**: http://www.crcn.in.th .
59. Description	Provide title or brief description of the linked page. If the page being linked is the protocol's home page on the sponsor's Web site, include the words "Click here for more information about this study:" and provide the name of the protocol.	[Free text] Limit to 254 characters
60. **Target Sample Size ***	Populated from "Target or Actual Number of Subjects" specified previously	[Free text]
61. **Date of First Enrollment ***	To be enable after the trial has been released. The actual date is required to be entered after the first enrollment had been done.	[Insert date in format dd/mm/yyyy]