CRIS

Clinical Research Information Service

* Mandatory data items for clinical research registration with WHO ICTRP

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* All data items are written in Korean including some terms in English. Most data items should be answered both in Korean and English.

DATA ITEM	DEFINITION/EXPLANATION
1. Background	
*CRIS registration number	This number is automatically assigned by the CRIS after the study is completely registered. It consists of the name of Primary Registry (KCT) and the 7 digit-number. ex. KCT 0000199 * Date of registration in primary registry: this date is automatically entered when the CRIS administrator assigns CRIS registration number.
†Unique protocol ID	This is the unique number rendered by study institute. If there is no such a number, the approval number of Institutional Review Board (IRB) or the study number appeared in IRB approval letter can be entered.
*Public/Brief title	Title intended for the lay people in easily understood language.
*Scientific title	Title appeared in the protocol approved by IRB.
Acronym	Enter the study acronym if available. Otherwise, leave the blank.
Whether or not the MFDS regulates the study?	Choose the appropriate answer from the list. ☐ Yes ☐ No
Whether or not the study protocol is IND/IDE protocol?	Choose the appropriate answer from the list. ☐ Yes ☐ No IND: Investigational New Drug Application IDE: Investigational Device Exemption
*Whether or not the study is registered with other Registry system besides the CRIS?	Choose the appropriate answer from the list. ☐ Yes ☐ No If the answer is yes, choose the name of the Registry system from the following list: ClinicalTrials.gov, ANZCTR, UMIN, ISRCTN and UTN. If the name of Registry system is not listed, choose 'Other' and then enter the name of Registry system. Enter the registration number assigned by the Registry system above.

2. Institutional Review Board/Ethics Committee	
†Board approval status	Only the study approved by the IRB can be registered with the CRIS. Choose the appropriate answer from the list. - Request not yet submitted: IRB approval is required, but has not yet been requested - Submitted, pending: approval has been requested, but not yet granted - Submitted, approval: approval has been requested and obtained - Submitted, exempt: approval has been requested and exemption has been granted - Submitted, denied: approval request has been denied - Submission not required: IRB approval is not required If 'Request not yet submitted,' 'Submitted pending,' or 'Submitted denied" is chosen, the study cannot be registered until the study is approved. If the study is conditionally approved, the condition should be satisfied and then the study can be registered with the CRIS.
†Board approval number	This number is assigned by the IRB when the study protocol is approved.
†Approval date	IRB approval date. Choose the date from the calendar and the date is entered in yyyy/mm/dd format.
†Approval letter upload	Upload the IRB approval letter. The following formats of the file are acceptable: hwp, doc, docx, jpg, gif, pdf and zip file. If the study is multicenter study, provide the approval letter of the IRB which is located in the affiliation of the principal investigator or the study site where the first subject is enrolled.
†Name of Board	Name of the IRB appeared in the IRB approval letter.
Whether or not the Data monitoring committee is formed	Choose the appropriate answer from the list. ☐ Yes ☐ No If the answer is yes, the name of the committee should be entered. The data monitoring committee 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 sponsors regarding the stopping of the trial for efficacy, for harms or for futility.
3. Contact Details	
*Contact person for principal investigator/ scientific queries	Name, telephone number and email address of the person who will respond to scientific queries about the study (e.g. principal investigator). Name and postal address of affiliation where this person is located.
*Contact person for public queries	Name, telephone number and email address of the person who will respond to general queries. Name and postal address of affiliation where this person is located.
†Contact person for updating information	Name, telephone number and email address of the person who registers the study and is in charge of updating the study information. Name and postal address of affiliation where this person is located.

4. Study Status	
Overall recruitment status	†○ Study Site Choose the appropriate answer from the list. ☐ Single center ☐ Multicenter *○ Recruitment status Choose the appropriate answer from the list. - Not yet recruiting: study subjects are not yet being recruited - Recruiting: study subjects are currently being recruited - Active, not recruiting: study is ongoing, but subjects are not currently being recruited or enrolled - Suspended: there is a temporary halt in recruitment, but it will potentially resume - Terminated: study subject recruitment or enrollment has halted and it will not resume - Completed: study subjects are no longer being recruited and no more intervention or observation is conducted - Withdrawn: study is halted prior to first enrollment If 'Suspended,' 'Terminated,' or 'Withdrawn' is chosen, provide the reason why the study is suspended, terminated or withdrawn. *○ Date of first enrollment/Status of first enrollment Choose the appropriate answer from the list. ☐ Anticipated ☐ Actual If the first enrollment takes place, enter the date of the first enrollment and choose 'actual' above. If the first enrollment will take place in the future, enter the anticipated date of the first enrollment and choose 'anticipated' above. In this case, if the enrollment actually takes place later on, enter the actual enrollment date. Choose the date from the calendar and the date is entered in yyyy/mm/dd format. *○ Target sample size Number of subjects that the study plans to enroll in total. ○ Primary completion date Date of the final intervention or observation for the final subject which will be conducted to measure primary outcome. Choose the appropriate answer from the list. ☐ Anticipated ☐ Actual If the final intervention or observation is actually conducted on a certain date, enter the actual date and choose 'actual' above. If it is not conducted yet, however, enter the anticipated date and choose 'anticipated' above. Choose the date from the calendar and the date is entered in yyyy/mm/dd format. ○ Study completion date Date when the final data collection is completed. Choose the appropriate answer from the list. ☐ Anticipated ☐ Actual

	If the final data collection is actually completed on a certain date, enter the actual date and choose ‘actual’ above. If it is not conducted yet, however, enter the anticipated date and choose ‘anticipated’ above. Choose the date from the calendar and the date is entered in yyyy/mm/dd format.
Recruitment status by participating study site(s)	†○ Name of study site Enter the name of each participating study site. Each participating study site should be entered in one box. Click ‘Add’ to add more boxes if multiple sites are participating. †○ Recruitment status Choose the appropriate answer from the list. - Not yet recruiting: study subjects are not yet being recruited - Recruiting: study subjects are currently being recruited - Active, not recruiting: study is ongoing, but subjects are not currently being recruited or enrolled - Suspended: there is a temporary halt in recruitment, but it will potentially resume - Terminated: study subject recruitment or enrollment has halted and it will not resume - Completed: study subjects are no longer being recruited and no more intervention or observation is conducted - Withdrawn: study is halted prior to first enrollment If ‘Suspended,’ ‘Terminated,’ or ‘Withdrawn’ is chosen, provide the reason why the study is suspended, terminated or withdrawn. †○ Date of first enrollment/Status of first enrollment Choose the appropriate answer from the list. ☐ Anticipated ☐ Actual If the first enrollment takes place, enter the date of the first enrollment and choose ‘actual’ above. If the first enrollment will take place in the future, enter the anticipated date of the first enrollment and choose ‘anticipated’ above. In this case, if the enrollment actually takes place later on, enter the actual enrollment date. Choose the date from the calendar and the date is entered in yyyy/mm/dd format. * Countries of recruitment: since all participating study sites should be entered, the countries of recruitment can be inferred from the name of participating institutes.
5. Source(s) of Monetary/Material Support	
*Organization name	Source of monetary or material support for the study (e.g. company, university, research institute, hospital, government). If there is no specific source, enter the name of affiliation of the principal investigator. Click ‘Add’ to add more boxes if the study has more than one source.

†Organization type	Choose the appropriate answer from the list. ☐ Pharmaceutical company ☐ Medical institute(e.g. hospital) ☐ Research institute ☐ University ☐ Government ☐ Others
Project ID	Number assigned by the source of monetary/material support. If there is no specific source, enter the unique protocol ID.
6. Sponsor organization	
*Organization name	The individual, organization, group or other legal entity which takes responsibility for initiating, managing and/or financing a study. * Secondary sponsor: if there is more than one sponsor, click 'Add' to add more boxes. If secondary sponsor agreed with the primary sponsor to take responsibilities of sponsorship, it is possible to change the information about sponsor.
†Organization type	Choose the appropriate answer from the list. ☐ Pharmaceutical company ☐ Medical institute(e.g. hospital) ☐ Research institute ☐ University ☐ Government ☐ Others
7. Study summary	
†Lay summary	Summary intended for the lay public in easily understood language. It includes, but not limited to, the following contents: (1) study purpose and background, (2) subjects, intervention and outcomes and (3) study hypothesis.
8. Study design	
*Study type	The study type is divided into two categories: interventional or observational study. Choose the appropriate study type from the list. ☐ Interventional ☐ Observational After the study type is chosen, the next step shows the page of chosen type only.
Interventional study	*○ Study purpose Choose the appropriate answer from the list. - Treatment: study is designed to evaluate one or more interventions for treating disease, sign, symptom, or health condition - Prevention: study is designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition - Diagnosis: study is designed to evaluate one or more interventions aimed at identifying a disease or health condition - Supportive care: study is designed to evaluate one or more interventions of which main purpose is not to treat disease, but to minimize side effects with maximum safety - Screening: study is designed to assess or examine methods of identifying disease in asymptomatic people - Health services research: study is designed to evaluate the health care system in terms of delivery, process, management,

	organization and financing - Basic science: study is designed to examine the basic mechanism of action of an intervention - Others *○ Phase Choose the appropriate phase of intervention from the list. - Not applicable: study which is not included in any category below - Phase 0: exploratory study without treatment or diagnosis purpose which involves very limited human exposure - Phase 1: initial study 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 - Phase 1/Phase 2: study is at a combined stage of phase 1 and 2 - Phase 2: controlled study to evaluate the effectiveness of a drug in patients with a specific disease or condition and to determine short term side effects and risks - Phase 2/Phase 3: study is at a combined stage of phase 2 and 3 - Phase 3: includes an expanded controlled and uncontrolled study after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to evaluate the overall benefit-risk relationship of new drug and to obtain additional information to suggest sufficient evidence for therapeutic standards - Phase 4: post marketing study to delineate additional information including risks, benefits, and additional efficacy of new drug after the drug is approved for marketing *○ Intervention model Choose the appropriate answer from the list. - Single group: all subjects are receiving the same intervention throughout the study - Parallel: different groups of subjects are receiving different interventions - Cross over: subjects are receiving all interventions in different sequences due to washout period - Factorial: study is designed to simultaneously test the effects of more than two interventions - Others *○ Blinding/Masking Knowledge of the interventions assigned to subjects. Choose the appropriate answer from the list. - Open: all involved in the study know the identity of the intervention assignment - Single blinding: subject or investigator is blinded - Double blinding: subject and investigator are blinded *○ Blinded subjects If blinded is chosen above, then tick who is/are blinded from the list. ☐ Subject ☐ Investigator ☐ Caregiver ☐ Outcome accessor

	*○ Allocation Choose the appropriate type of allocation to intervention from the list. - Randomized controlled trial(RCT): allocation of subjects into different groups was random or by a method based on chance. - Nonrandomized controlled trial(Non-RCT): allocation of subjects into different groups is expressly or deliberately done, and is not random or by chance. - Not applicable *○ Intervention type Choose the appropriate type of intervention from the list. ☐ Drug ☐ Medical Device ☐ Biological/Vaccine (☐ Stem cell ☐ Non Stem cell) ☐ Procedure/Surgery ☐ Radiation ☐ Behavioral ☐ Genetic ☐ Dietary Supplement ☐ Others *○ Intervention description Describe the intervention in detail (e.g. if intervention is a drug, describe the name, administration dosage, frequency, duration and route). If there is more than one intervention, describe the difference between interventions. ○ Arm Describe the following items in detail for each arm. Click 'Add' to add more boxes if there are multiple arms. - Number of arm †- Arm label †- Target sample size †- Arm type: choose the appropriate type of arm from the list. • Experimental group: group receiving the intervention of which the study is intended to prove the effectiveness. • Active comparator: group receiving standard or active intervention to which the study intervention is compared. • Placebo comparator: group receiving inactive intervention(e.g. tablet form) to which the study intervention is compared. • Sham comparator: group receiving faked procedure or surgery to which the study procedure or surgery is compared. • No intervention • Others †- Arm description Describe the intervention in detail (e.g. if intervention is a drug, describe the name, administration dosage, frequency, duration and route). If there is more than one intervention, describe the difference between interventions.
Observational study	†○ Observational study model Choose the appropriate model from the list. - Cohort: group of individuals, initially defined and composed, with common characteristics, who are examined or traced over a given time period - Case-control: group of individuals with specific characteristics (or that are exposed to certain environment) compared to group(s) with different characteristics but otherwise similar

	- Case-only: single group of individuals with specific characteristics - Case-crossover: the characteristics of a group at one point immediately prior to occurrence of disease are compared to the characteristics of the same group at a prior time - Ecologic or community studies: group of individuals with the same geographical characteristics is compared to other groups in terms of various environmental factors or international measurement standards. - Family-based: study is conducted among family members (e.g. genetic researches with family members, twin studies, and family environment studies) - Others †○ Time perspective Choose the appropriate timing of study from the list - Prospective: study that observes the subjects in real time (may also occur in the future) and collects relevant data. - Retrospective: study that observes past events of the subjects and collects relevant data. - Cross-sectional: study that observes the subjects at one point in time during a particular period of time - Others †○ Target sample size ○ Cohort/Group Describe the following items in detail for each group. Click 'Add' to add more boxes if there are multiple groups. - Number of Cohort/Group †- Cohort/Group label †- Cohort/Group description Describe what the study is intended to observe for each group in detail. †○ Biospecimen collection and archiving Choose the appropriate answer from the list. - None retained - Retained: sample with DNA - Retained: sample without DNA †○ Biospecimen description Enter all types of biospecimen to be retained or retained (e.g. whole blood, serum, white blood cell, urine, tissue)
9. Subject eligibility	
Interventional study	*○ Condition(s)/Problem(s) Choose the appropriate category from the list. This category is based on International Classifications of Disease (ICD, 10th version). - Certain infectious and parasitic diseases - Neoplasms

	- Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism - Endocrine, nutritional and metabolic diseases - Mental and behavioral disorders - Diseases of the nervous system - Diseases of the eye and adnexa - Diseases of the ear and mastoid process - Diseases of the circulatory system - Diseases of the respiratory system - Diseases of the digestive system - Diseases of the skin and subcutaneous tissue - Diseases of the musculoskeletal system and connective tissue - Diseases of the genitourinary system - Pregnancy, childbirth and the puerperium - Certain conditions originating in the perinatal period - Congenital malformations, deformations and chromosomal abnormalities - Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified - Injury, poisoning and certain other consequences of external causes - External causes of morbidity and mortality - Factors influencing health status and contact with health services - Code for special purposes - Others After choosing the category above, then enter the description of health problem(s) using MeSH terminology (http://www.nlm.nih.gov/mesh/). ○ Whether or not the condition/problem is rare disease? Choose the appropriate answer from the list. ☐ Yes ☐ No *○ Inclusion criteria - Gender: choose the appropriate answer from the list. ☐ Male ☐ Female ☐ Both - Age: enter the appropriate numbers in the blanks for minimum and maximum ages. Minimum ( ) (choose the unit: no limit, year, month, day) ~ Maximum ( ) (choose the unit: no limit, year, month, day) - Describe the inclusion criteria other than gender and age in detail. *○ Exclusion criteria Describe the exclusion criteria in detail. ○ Whether or not healthy volunteers are included? Choose the appropriate answer from the list. ☐ Yes ☐ No
Observational study	†○ Study population description Describe the study population in detail.

†○ Sampling method

Describe the sampling method in detail by referring to the explanation as follows:

- Probability sampling: method that selects the subjects from study population with a certain rate of probability and that includes simple random sampling, systemic random sampling, cluster random sampling, etc.
- Non-probability sampling: method that selects the subjects from study population without consideration of probability and that includes convenience sampling, purposive sampling, etc.

*○ Condition(s)/Problem(s)

Choose the appropriate category from the list. This category is based on International Classifications of Disease (ICD, 10th version).

- Certain infectious and parasitic diseases
- Neoplasms
- Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism
- Endocrine, nutritional and metabolic diseases
- Mental and behavioral disorders
- Diseases of the nervous system
- Diseases of the eye and adnexa
- Diseases of the ear and mastoid process
- Diseases of the circulatory system
- Diseases of the respiratory system
- Diseases of the digestive system
- Diseases of the skin and subcutaneous tissue
- Diseases of the musculoskeletal system and connective tissue
- Diseases of the genitourinary system
- Pregnancy, childbirth and the puerperium
- Certain conditions originating in the perinatal period
- Congenital malformations, deformations and chromosomal abnormalities
- Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified
- Injury, poisoning and certain other consequences of external causes
- External causes of morbidity and mortality
- Factors influencing health status and contact with health services
- Code for special purposes
- Others

After choosing the category above, then enter the description of health problem(s) using MeSH terminology (http://www.nlm.nih.gov/mesh/).

○ Whether or not the condition/problem is rare disease?

Choose the appropriate answer from the list.

☐ Yes ☐ No

*○ Inclusion criteria

- Gender: choose the appropriate answer from the list.

  ☐ Male ☐ Female ☐ Both

- Age: enter the appropriate numbers in the blanks for minimum and maximum ages.

  Minimum ( ) (choose the unit: no limit, year, month, day) ~
  Maximum ( ) (choose the unit: no limit, year, month, day)

	- Describe the inclusion criteria other than gender and age in detail. *○ Exclusion criteria Describe the exclusion criteria in detail. ○ Whether or not healthy volunteers are included? Choose the appropriate answer from the list. ☐ Yes ☐ No
10. Outcome Measure(s)	
Primary outcome(s)	Primary outcome(s) is the main outcome used to determine the effects of the intervention(s). †○ Type of primary outcome Choose the appropriate type of primary outcome from the list. - Safety - Efficacy - Safety/Efficacy - Bio-equivalence - Bio-availability - Pharmacokinetics - Pharmacodynamics - Pharmacokinetics/dynamics - Clinical-equivalence - Not applicable *○ Name and timepoint(s) of primary outcome Enter only one primary outcome in the primary outcome box. Click 'Add' to add more boxes if there is more than one primary outcome. Provide specific name of primary outcome and do not use abbreviation.
Secondary outcome(s)	*○ Name and timepoint(s) of secondary outcome Secondary outcome(s) is outcome(s) which is of secondary interest or that is measured at timepoints of secondary interest. Enter only one secondary outcome in the secondary outcome box. Click 'Add' to add more boxes if there is more than one secondary outcome. Provide specific name of secondary outcome and do not use abbreviation.
11. Publication	
Publication	If there is any publication associated with the study registered, enter the number of publication including author name, title, journal name and publication date. When entering the journal name, tick whether the journal is included in SCI or not.