**Appendix 1** The quality assessment standard of modified Trial Registration Data Set (V.1.3.1)

| Item | Explanatory text | Score |
|---|---|---|
| Primary Registry and Trial Identifying Number | Name of Primary Registry, and the unique identity number assigned by the Primary Registry to this trial | 1 |
| Date of Registration in Primary Registry | Date when trial was officially registered in the Primary Registry | 1 |
| Secondary Identifying Numbers | An identifier(s) (ID), if any, other than the organization's Unique Protocol Identification Number or the NCT number that is assigned to the clinical study. This includes any unique clinical study identifiers assigned by other publicly available clinical trial registries. | 1 |
| Study Sponsor (Primary Sponsor) | The entity (for example, corporation or agency) that initiates the study | 1 |
| Collaborators (Secondary Sponsor) | Other organizations (if any) providing support. Support may include funding, design, implementation, data analysis or reporting. The responsible party is responsible for confirming all collaborators before listing them. | 1 |
| Contact for Principal Investigators | The individual designated as responsible party by the sponsor, the contact for PI must therefore include: name and title, email address, telephone number, postal address and affiliation. One point will be given for each information provided. | 6 |
| Public Title | Title intended for the lay public in easily understood language. The title should include, where possible, information on the participants, condition being evaluated, and intervention(s) studied. | 1 |
| Scientific Title | The title of the clinical study, corresponding to the title of the protocol. | 1 |
| Countries of Recruitment | The countries from which participants will be, are intended to be, or have been recruited at the time of registration. | 1 |
| Health Condition or Problem Studied | Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study. | 1 |
| Arm, Groups, and Interventions | Arm for interventional studies (3 points)<br>• Arm title: the short name used to identify the arm.<br>• Arm Type: the role of each arm in the clinical trial. For example, experimental, active comparator, placebo comparator, sham comparator, no intervention, or other.<br>• Arm Description: Additional descriptive information (including which interventions are administered in each arm) to differentiate each arm from other arms in the clinical trial.<br>Groups for observational studies (2 points)<br>• Group/Cohort Label: the short name used to identify the group.<br>• Group/Cohort Description: explanation of the nature of the study group (for example, those with a condition and those without a condition; those with an exposure and those without an exposure).<br>Interventions (1 point)<br>• Specify the intervention(s) associated with each arm or group for interventional studies. Specify the exposure(s) of interest for observational studies. Including intervention type, intervention name, intervention description (For example, interventions involving drugs may include dosage form, dosage, frequency, and duration). | 4 for interventional studies;<br>3 for observational studies |
| Key Inclusion and Exclusion Criteria | For interventional and observational studies (5 points)<br>• Sex/Gender: all; female; male.<br>• Age Limits: minimum age and maximum age.<br>• Accepts Healthy Volunteers: select Yes/No.<br>• Inclusion Criteria: relate to clinical diagnosis and co-morbid conditions.<br>• Exclusion Criteria: to ensure patient safety.<br>For observational studies only (2 points)<br>• Study Population Description: description of the population from which the groups or cohorts will be selected.<br>• Sampling Method: select Probability Sample/Non-Probability Sample. | 5 for interventional studies;<br>7 for observational studies |
| Study Type | For interventional studies (7 points)<br>• Type of study<br>• Study design<br>• Primary Purpose: the main objective of the intervention(s) being evaluated by the clinical trial. (Select one: treatment; prevention; diagnostic; supportive care; screening; health services research; basic science; device feasibility; or other).<br>• Study Phase: the numerical phase of drug product clinical trial (Select one: N/A; Early Phase 1; Phase 1; Phase 1/Phase 2; Phase 2; Phase 2/Phase 3;Phase 3; Phase 4).<br>• Interventional Study Model: the strategy for assigning interventions to participants (Select one: single group; parallel; crossover; factorial; sequential).<br>• Masking: masking/no masking (if masking, select one: participant; care provider; investigator; outcomes assessor).<br>• Allocation: the method by which participants are assigned to arms in a clinical trial. N/A for a single-arm trial; randomized; nonrandomized.<br>• Allocation concealment: description of allocation concealment mechanism.<br>For observational studies(6 points)<br>• Type of study<br>• Study design<br>• Observational Study Model: primary strategy for participant identification and follow-up (Select one: cohort; case-control; case-only; case-crossover; ecologic or community studies; family-based; or other).<br>• Time Perspective: temporal relationship of observation period to time of participant enrollment (Select one: retrospective; prospective; cross-sectional; or other).<br>• Biospecimen Retention: indicate whether samples of material from research participants are retained in a biorepository (Select one: no samples retained; samples with DNA retained; samples without DNA retained.<br>• Biospecimen Description: specify all types of biospecimens to be retained (e.g., whole blood, serum, white cells, urine, tissue).<br>• Target Follow-Up Duration: the anticipated time period over which each participant is to be followed. Provide a number and select a Unit of Time (years, months, weeks, days). | 7 for interventional studies;<br>6 for observational studies |
| Date of First Enrollment | The estimated date on which the clinical study will be open for recruitment of participants, or the actual date on which the first participant was enrolled. | 1 |
| Sample Size | Sample Size consists of:<br>• Number of participants that the trial plans to enroll in total.<br>• Number of participants that the trial has enrolled. | 2 |
| Recruitment Status | Recruitment status of this trial: not yet recruiting; recruiting; enrolling by invitation; active, not recruiting; completed; suspended; terminated; withdrawn. | 1 |
| Primary Outcome(s) | A description of each primary outcome measure. For observational studies, specific key measurement or observation used to describe patterns of diseases or traits or associations with exposures, risk factors or treatment, including:<br>• The name of the outcome (do not use abbreviations)<br>• The metric or method of measurement used (be as specific as possible)<br>• The timepoint(s) of primary interest | 3 |
| Key Secondary Outcomes | Secondary outcomes are outcomes which are of secondary interest or that are measured at timepoints of secondary interest.<br>• The name of the outcome (do not use abbreviations)<br>• The metric or method of measurement used (be as specific as possible)<br>• The timepoint(s) of primary interest | 3 |
| Completion date | The date on which the final data for a clinical study were collected (for example, last participant's last visit). | 1 |
| Summary Results | It consists of:<br>• Date of posting of results summaries.<br>• URL hyperlink(s) related to results and publications.<br>• Baseline Characteristics: 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.<br>• 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.<br>• 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.<br>• Primary outcome measures: A table of data for each primary outcome measure and their respective measurement of precision.<br>• Primary outcome statistical analyses: The result(s) of scientifically appropriate statistical analyses that were performed on the outcome measure data.<br>• Secondary outcome measures: A table of data for each secondary outcome measure and their respective measurement of precision.<br>• Secondary outcome statistical analyses: The result(s) of scientifically appropriate statistical analyses that were performed on the outcome measure data.<br>• Brief summary. | 10 |
| IPD sharing statement | Indicate whether there is a plan to make individual participant data (IPD) collected in this study, including data dictionaries, available to other researchers (typically after the end of the study).It consists of:<br>• Plan to share IPD (Yes, No, Undecided)<br>• Available IPD/Information Type: Individual Participant Data Set; Study Protocol; Statistical Analysis Plan; Informed Consent Form; Clinical Study Report; Analytic Code; Other (specify). | 2 |
| Data Monitoring Committee | Indicate whether a data monitoring committee has been appointed for this study. Select Yes/No. | 1 |


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