

## ***1. Primary Registry and Trial Identifying Number***

Name of Primary Registry, and the unique ID number assigned by the Primary Registry to this trial.

## ***2. Date of Registration in Primary Registry***

Date when trial was officially registered in the Primary Registry.

## ***3. Secondary Identifying Numbers***

Other identifying numbers and issuing authorities besides the Primary Registry, if any. Include the sponsor name and sponsor-issued trial number (e.g., protocol number) if available. Also include other trial registries that have issued an identifying number to this trial. There is no limit on the number of Secondary identifying numbers that can be provided.

## ***4. Source(s) of Monetary or Material Support***

Major source(s) of monetary or material support for the trial (e.g., funding agency, foundation, company).

## ***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.

## ***6. Secondary Sponsor(s)***

Additional individuals, organizations or other legal persons, if any, 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.

## ***7. Contact for Public Queries***

Email address, telephone number, or postal address of the contact who will respond to general queries, including information about current recruitment status.

## **8. Contact for Scientific Queries**

Email address, telephone number, or postal address, 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-center study, enter the contact information for the lead Principal Investigator or overall scientific director.

## **9. Public Title**

Title intended for the lay public in easily understood language.

## **10. Scientific Title**

Scientific title of the study as it appears in the protocol submitted for funding and ethical review. Include trial acronym if available.

## **11. Countries of Recruitment**

The countries from which participants will be, are intended to be, or have been recruited.

## **12. 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. 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.

## **13. Intervention(s)**

Enter the specific name of the intervention(s) and the comparator/control(s) being studied. 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").

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 each intervention, describe other intervention details as applicable (dose, duration, mode of administration, etc).

## **14. Key Inclusion and Exclusion Criteria**

Inclusion and exclusion criteria for participant selection, including age and sex.

## **15. Study Type**

A single arm study is one in which all participants are given the same intervention. Trials in which participants are assigned to receive one of two or more interventions are NOT single arm studies. Crossover trials are NOT single arm studies.

A trial is "randomized" if participants are assigned to intervention groups using a method based on chance (e.g., random number table, random computer-generated sequence, minimization, adaptive randomization).

## **16. Date of First Enrollment**

Anticipated or actual date of enrollment of the first participant.

## **17. Target Sample Size**

Number of participants that this trial plans to enroll.

## **18. Recruitment Status**

Recruitment status of this trial:

- Pending: participants are not yet being recruited or enrolled at any site
- Recruiting: participants are currently being recruited and enrolled
- Suspended: there is a temporary halt in recruitment and enrollment
- Complete: participants are no longer being recruited or enrolled
- Other

## **19. Primary Outcome(s)**

Outcomes are events, variables, or experiences that are measured because it is believed that they may be influenced by the intervention. The Primary Outcome should be the outcome used in sample size calculations, or the main outcome(s) used to determine the effects of the intervention(s).

Enter the names of all primary outcomes in the trial as well as the pre-specified timepoint(s) of primary interest. Be as specific as possible with the metric used (e.g., “% with Beck Depression Score > 10” rather than just “depression”).

Examples: Outcome Name: all-cause mortality, Timepoints: 5 years; or Outcome Name: Mean Beck Depression Score, Timepoint: 18 weeks

## **20. Key Secondary Outcomes**

Secondary outcomes are events, variables, or experiences that are of secondary interest or that are measured at timepoints of secondary interest. A secondary outcome may involve the same event, variable, or experience as the primary outcome, but measured at timepoints other than those of primary interest (e.g., Primary outcome: all-cause mortality at 5 years; Secondary outcome: all-cause mortality at 1 year, 3 years), or may involve a different event, variable, or experience altogether (e.g., Primary outcome: all-cause mortality at 5 years; Secondary outcome: hospitalization rate at 5 years).

Enter the name and timepoint(s) for all secondary outcomes of clinical and/or scientific importance. Be as specific as possible with the metric used (e.g., “% with Beck Depression Score > 10” rather than just “depression”).

Examples: Outcome Name: all-cause mortality, Timepoint: 6 months, 1 year; or Outcome Name: Mean glycosylated hemoglobin A1C, Timepoint: 4 and 8 weeks