OBJECTIVES and OUTCOME MEASURES for CLINICAL STUDY PROTOCOLS

Study objectives are distinct from study outcome measures, both defined below. Primary outcome measure(s) should correspond to the primary objective(s), and secondary outcome measures should correspond to the secondary objectives.

Objectives (sometimes also called aims) are concise statements of the scientific questions that the study is designed to answer. Express each objective as a statement of purpose (e.g., to assess, to determine, to compare, to evaluate) and include the general purpose (e.g., efficacy, effectiveness, safety) and/or specific purpose (e.g., dose-response, superiority to placebo, effect of an intervention on disease incidence, disease severity, or health behaviour).

Outcome measures (also called endpoints) are specific measurements or observations (e.g., specific laboratory tests that define safety or efficacy, clinical assessments of disease status, assessments of psychological characteristics, patient reported outcomes, behaviors or health outcomes) that are used to assess the effect of the study intervention. Include the study visits or time points at which data will be recorded or samples will be obtained. A general formula for an outcome measure is: [Thing being measured] as assessed by [type of assessment] at [timepoint(s)]. The protocol should list primary outcomes and secondary outcomes and time points for each outcome measure.

Example Outcome Measures:

- Systolic blood pressure as assessed by blood pressure cuff at baseline, week 1, month 1
- Quality of Life as assessed by the SF-36 survey at baseline and year 1. Total score ranges from 0 to 100, with a higher score indicating a better outcome.
- Pain as Assessed by a Visual Analogue Scale (VAS) at day 30
- Level of IL-6 protein as assessed by ELISA at baseline, week 1, and week 6
- Tumor size as assessed by magnetic resonance imaging (MRI) at 1 year
- Number of participants with disease progression as assessed by magnetic resonance imaging (MRI) at baseline and 1 year
- Number of participants with hypoxia as assessed by continuous pulse oximetry at 10 minutes after administration of drug
- Number of participants who were re-hospitalized for heart failure (from the time of randomization to day 30 after randomization)
- Number of participants who are complication free at 1 year after surgery
- Number of Ventilator-free days (VFD) between the time of enrollment and the time of discharge (about 28 days)
- Tolerability as assessed by the number of patients who stay on the study medication (end of intervention period of 6 months)
- Feasibility as assessed by number of participants who complete all follow-up visits (end of follow up period of 1 year)
- Patient satisfaction as assessed by score on a satisfaction questionnaire (end of follow up period of 6 months)
- Change in cognitive impairment as measured by the Montreal Cognitive Assessment (MoCA), assessed at baseline and 6 months. Total score ranges from 0 to 30, with a higher score indicating a better outcome.

For further guidance on objectives and outcome measures, see pages 9-11 of the NIH/FDA clinical trial protocol template at this link.