

SAMPLE OF OBJECTIVES

Please be aware that often times, objectives from a grant need to be modified to create evaluable, measurable endpoints.

Primary Objective Statements:

Please only include one primary objective.

Example:

- To determine the maximum tolerated dose of [Agent X] given in conjunction with [Agent Y] in subjects with [Disease X] / Stage by measuring [Factor X] and [Factor Y].

Example:

- To evaluate the safety and tolerability of [Agent X] in combination with [Agent Y] by measuring [Factor X] and [Factor Y].

Secondary Objective Statements:

Example:

- To determine the dose limiting toxicities of the combination of [Agent X] and [Agent Y] by comparing [Factor X] and [Factor Y].

Correlative Objective Statements:

Example:

- To determine the pharmacokinetics of [Agent X] when given in combination with [Agent Y] by measuring [Factor X] and [Factor Y].

Example:

- To evaluate the efficacy and pharmacokinetics of [Agent X] in combination with [Agent Y] by comparing [Factor X] and [Factor Y].

Correlative Endpoints:

Example:

- To describe any preliminary evidence of clinical activity of this combination (complete response (CR) rate) in [Disease X].
- To determine the median CD74 antigen expression in patients achieving a response versus those patients not achieving a response.

Example:

- To determine the effects of two different doses of oral [Agent X] on levels of expression of [biomarker X], [biomarker Y], and [biomarker Z] on patients with newly diagnosed [Disease X].