

Eligibility Criteria Reference Document: Carefully consider whether each criterion is necessary for this particular study. Please make every effort to be as broad as possible in defining eligible patients, and only exclude those patients for whom there is risk associated with mechanism of action of the treatment(s) and known/expected toxicities.

For example, to increase enrollment, if a study drug is not myelosuppressive, consider having less stringent parameters, or eliminating exclusion/inclusion criteria for absolute neutrophil count and platelet count. If a study drug is hepatically cleared and not nephrotoxic, then a higher limit for serum creatinine may be appropriate.” This may increase enrollment of patients with comorbidities such as renal insufficiency, which is more likely to affect African American patients.

Examples of commonly used eligibility criteria:

Example: Subjects must have histologically or cytologically confirmed Name of Disease.

Please specify eligible disease(s)/stage(s)/prognostic score(s) as well as if staging is pathological or clinical. If histology or cytology must be confirmed, then a biopsy from a metastatic site cannot be used unless it states the origin....if you need histology from a metastatic site together with imaging, then indicate here.

Example: Subjects must have histologically confirmed [Disease X] that has relapsed or refractory to standard curative treatment or for which no standard treatment exists.

Example: Subjects treated for brain metastases are eligible if the subject has been neurologically stable for at least 1 month.

Example: Subjects must have measurable disease according to RECIST 1.1.

Example: The investigator must state a medical or scientific reason if subjects who are HIV-positive will be excluded from the study.

Suggested text is provided below:

HIV-positive subjects on combination antiretroviral therapy are ineligible because of the potential for pharmacokinetic interactions with Agent X. In addition, these subjects are at increased risk of lethal infections when treated with marrow suppressive therapy. Appropriate studies will be undertaken in subjects receiving combination antiretroviral therapy when indicated. . Also include whether HIV testing is required for this study, or only if a known diagnosis will be excluded.

Example: The investigator must state a medical or scientific reason if pregnant or nursing subjects will be excluded from the study.

Suggested text is provided below:

Pregnant or breastfeeding women are excluded from this study because Agent X is Name of Agent Class agent with the potential for teratogenic or abortifacient effects. Because

there is an unknown, but potential risk for adverse events in nursing infants secondary to treatment of the mother with Agent X, breastfeeding should be discontinued if the mother is treated with Agent X. These potential risks may also apply to other agents used in this study.

Example: Subjects with any condition or behavior that in the judgment of the investigator, would compromise the subject's ability to participate in the study and/or comply with study procedures.

Example: Subjects must be disease free of prior invasive malignancies for > 5 years, with the exception of curatively treated basal cell or squamous cell carcinoma of the skin or cancer in-situ of the cervix.

Example: Women of childbearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry and for the duration of study participation. Should a woman become pregnant or suspect she is pregnant while participating in this study, she should inform her treating physician immediately.

Example: All prior treatment-related toxicities must have resolved \leq grade 1, with the exception of [insert expected toxicities that may be > grade; i.e. alopecia]

Example: Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements.

Example: Subjects with known hypersensitivity to [Agent X] or its components, including [XXX].

Example: Pregnant and lactating women are excluded from this study.

Example: Sex (defined as a person's classification as male or female based on biological distinctions)

Example: Gender based (defined as self-representation of gender identity). If eligibility is based on gender describe gender criteria.

Example: Subjects receiving any medications or substances that are inhibitors or inducers of (specify CYP450 enzyme(s)) are ineligible. Lists including medications or substances known or with the potential to interact with the (specify CYP450 enzyme(s) CYP450 enzyme(s) Xisoenzymes are provided in Appendix _____.