General
1. Terminology

**SLIDE**

**Terminology: Studies of Ocular Complications of AIDS (SOCA)**

**Default language**
- Patient for persons studied
- Treatment (any treatment group including placebo treatment)
- Outcome or outcome measure (as opposed to event, endpoint)
- Variable (as opposed to parameter)
- Center director (as opposed to principal investigator)
- Study treatment (any of the assigned treatment regimens)
- Test treatment (any of the assigned treatments, except control treatments)
- Control treatment (placebo treatment)

**Terms avoided**
- Treatment failure (presumptive)
- Informed consent (wishful thinking in the absence of information to indicate that consent is truly informed)
- Endpoint (operational implications usually inconsistent with requirements for continued followup)
- Placebo (as an adjective, e.g., as in placebo patients, or as a synonym for no treatment)
- Subject (condescending)
- Drop-in (at odds with analysis by original treatment assignment)

**NARRATIVE**

Good research requires precision of language. The practice of using different terms to mean the same thing may be a valued practice for poets and writers and for radio and TV announcers, but not for researchers. The use of different words to mean the same thing in study protocols and publications is confusing.

Troublesome terms in trials include dropout, drop-in, endpoint, missed visit, and treatment failure. Concepts not well understood and subject to misuse include the notation of stratification versus subgroup analysis, subgroup analysis vs data dredging, randomization, internal validity versus external validity, bias (e.g., selection bias vs. treatment-related bias), and “statistical significance.”

Some terms are best avoided in trials because of their multidisciplinary nature and especially in multicenter trials. For example, investigator as a synonym for clinician investigator (investigatorship is not limited to the clinical side of activities in trials)
and principal investigator (PI) in multicenter trials where there are as many “principal” investigators as there are centers.

**QUESTIONS**

- What practices do you intend to follow to standardize terminology?
- Do you have a list of terms to be avoided? If not, should you prepare such a list?
- Do you have operational definitions for enrolled (randomized), dropout, and missed visits?
- Are you planning to produce a glossary of terms and definitions for inclusion in the trial handbook? If yes, who will produce it and who will maintain it?