Session 3

May 10, 2012 Advisory Committee FTC/TDF for PrEP

- A “bonus” question that did not get answered due to time constraints.
- How does FDA approval of FTC/TDF for PrEP affect future development of other prevention methods including oral drugs and microbicides?

Things to Consider

- Possible differences in opinions among regulatory jurisdictions about the approval/approvability of FTC/TDF for PrEP
- Availability may be limited globally (cost, regulatory approval, acceptance)
- Approval doesn't mean it is the right choice for everyone or should be used by everyone or every risk category
- Not including FTC/TDF in future trials presents potential ethical issues
  - similar for oral drugs and topical microbicides but clinical trial approaches may differ

Where does FTC/TDF fit in future trials? Potential Options (to Provoke Discussion):

- Add-On: New Treatment + FTC/TDF vs. FTC/TDF + Placebo
- Active Control: New Treatment vs. FTC/TDF
- Placebo-controlled Trial, BUT, Offer Truvada as an option for background treatment along with condoms and counseling according to local practices.
  - all sites must offer it or some sites may choose not to offer it
- Placebo-controlled trial in individuals who don't want to take FTC/TDF
- Placebo-controlled trial evaluating topical microbicides
  - "no need to offer FTC/TDF because it is oral and the investigational drug is topical"

Challenges

- Sample size large in options where FTC/TDF is used uniformly as background treatment
- If FTC/TDF only used by some participants, how do we deal with the heterogeneity? Can subset analysis of those who did not use FTC/TDF save a marginally positive analysis in all randomized?