Clinician Breakout

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Clinician breakout sessions

- Clinician's role in recruitment, retention & product adherence
- Role of PSRT in safety monitoring
- Adverse events Reporting session
- Session on preparation for MTN 015

Clinician's role in recruitment, retention & product adherence

Objective

- To enhance the role of clinicians in study recruitment, retention & product adherence

Recruitment

- Incorporation of the male involvement agenda right in protocol budget development processes, at community entry for new protocols & thru trial implementation
    - identification of key stakeholders for stimulating dialogue on microbicide research
    - Developing site specific strategies for engaging & motivating men coming to study clinic visits (Male peer group concept)
    - Male involvement is key for microbicide success

Recruitment

- Monitoring recruitment efforts for high risk women very critical
    - Sites resolved to adopt the GPS system (Durban) or some less sophisticated community mapping techniques
    - Pay particular attention to HIV incidence as a way of monitoring appropriateness of recruitment efforts (avoid getting lost in the bigger picture)

Retention

- Participant retention meetings (Harare)
    - Involving participants in finding solutions to major retention challenges
- Partners' meetings.
- Ongoing community sensitization meetings.

Product adherence

- Little things make a big difference for both retention & adherence
- Always keep your eyes open & ears to the ground (participant meetings enhance process)
- Use small surveys (e.g. FGD's) to more understanding of reasons behind poor product adherence (tote bag example in Lilongwe only came to site's attention thru such surveys)
- Returning used applicators (for future trials) enhances reporting/accountability & may enhance adherence (Blantyre site using approach)

Adverse Events Reporting session

- Standardization of approach to reporting lab AE's which turn out to be lab errors
  - Resolve AE versus deleting it
  - Repeating the labs as soon as possible was preferred
- Reporting abnormal labs closely related to defined clinical condition as separate AE's will continue to dependent on clinicians judgment of extent of association
  - Malaria & low Hemoglobin
- Need to align reporting requirements with clinical judgment
  - Abnormal PAP smears followed with histological confirmation

PSRT session

- Sites generally happy with response process & timeliness
- Need to create/enhance use of FAQ for common PSRT queries (reduces frequency of engaging PSRT)
- Sites noted that there might be need to share safety information for studies of same product (not just DSMB findings as is case with MDP 301 & #035)
    - ? Feasibility of using DAIDS toxicity tables for studies of same product
    - Having similar safety review process studies of same product

MTN 015 session

Key challenges

- some ethical boards may require pregnant sero-converters to have more than local standard of care for PMTCT (combination therapy preferred to mono-therapy)

- Infants of sero-converters who test HIV positive
    - suggestion to explore options for inclusion of sero-converters into other ongoing protocols at sites CHAVI, ACTG etc)