HPTN SMC

JIM HUGHES, CHAIR
SCHARP
Role in the HPTN

• Provides internal peer review of study conduct of HPTN trials
  – Accrual
  – Retention
  – Delivery of intervention
  – Data Management
  – Laboratory QA/QC

• If no DSMB, SMC also provides ongoing safety review

• Chair, standing members (representing core, stat, lab, funders) and ad-hoc members (study-specific, often HPTN investigators)

• Reports to the EC
Procedures

• Each study reviewed every 4 – 6 months
  – Safety may be tracked more frequently
    • Individual level data by site investigators, CMC
    • MO reviews reportable SAE’s
    • On some protocols one SMC member may be designated to
      review aggregate safety data more often; can alert full SMC if
      issues arise
• Open and closed reports prepared by SCHARP
• Open session discussion with study team followed
  by closed session
• Recommendations sent to study team, copied to EC
Activity (6/13 – 5/14)

- 10 reviews
  - 052  11/13
  - 065  1/14
  - 067  9/13, 1/14
  - 068  9/13, 1/14
  - 069  8/13, 2/14
  - 073  2/14
  - MTN020  5/14

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