The “Quick” Clinical Trials Working Group (QWG) & the MTN: Thoughts Going Forward

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Microbicide Trials Network (MTN) Annual Meeting—Plenary Session
Washington, DC, 26 March 2007
QWG Mandate

Established following April 2004 meeting of Microbicide Donors’ Committee to:

• promote exchange of knowledge, experience, data, ideas, & problems among investigators of current effectiveness trials

• ensure that, if none of current late-stage candidate microbicides sufficiently effective for licensure, there will be maximal learning from design, implementation, analysis, & results of those trials
QWG Structure

Co-Chairs:
• Salim Abdool Karim, Pro Vice-Chancellor for Research, University of KwaZulu-Natal
• Janet Darbyshire, Director, Clinical Trials Unit, UK Medical Research Council

Membership:
• Investigators, current or planned microbicide effectiveness trials; statisticians; behavioral scientists; & guests as invited

Secretariat:
• Alliance for Microbicide Development
Five meetings to date:

• 15-16 November 2004, Washington, DC, USA
• 10-11 May 2005, New York City, USA
• 16-17 November 2005, Chapel Hill, USA
• 27 April 2006, Cape Town, South Africa
• 23-24 January 2007, London, UK
QWG Meeting Structure & Focus

Each meeting includes:
- Update on status of trials being implemented/designed by each member
- Updates to now-standard set of tabular analytical summaries of protocol elements
- In-depth discussion of challenges, solutions, & topics identified as relevant & timely by co-chairs & members
• potential for meta-analysis of endpoint & safety data across studies of identical or similar products
• developing overarching “Super”-DMC
• MMCI & communication strategies
• use of biomarkers in trials
• determining incidence prior to & during trials
• statistical/ethical implications of current trial completion
• standard of care at trial sites
• statistical & behavioral issues around measuring/ maximizing adherence to protocol & product use
• proposal for alternative microbicide trial design activity
5th meeting explored statistical & ethical implications of completing current trials

4 potential scenarios: completed trial(s) show(s) . . .

• Harm
• No benefit or harm
• Benefit insufficient for licensure, or confusing result
• Benefit sufficiently compelling as public health and/or personal prevention intervention

Next QWG meeting to pursue, departing from forthcoming PopCouncil plan re Carraguard trials
5th meeting also addressed feasibility & next steps for proposed “Alternative Trial Designs” activity

GOAL: To identify/explore novel designs for microbicide trials able to address challenges identified in QWG meetings & anticipated challenges

• 3 guest statisticians at 5th meeting made substantial contributions & will continue involvement
• QWG supports moving forward with this, conference calls since, planning underway

Preparation of prototype designs, analysis, discussion at next QWG meeting, June 2007 (TBC)
QWG/MTN Collaborations

Full membership in QWG & all its activities

Active collaboration in “Alternative Trial Designs” (& prototypes)

Identification/pursuit of issues through/around which QWG might enhance coordination of MTN clinical trials portfolio with other microbicide trials groups
Acknowledgments

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