



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



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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**



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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



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QWG Meetings

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**



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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



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Topics Addressed

- 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



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Going Forward

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



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Going Forward (cont.)

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)



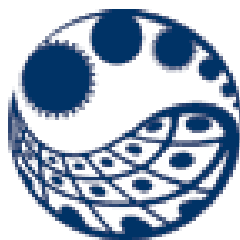
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QWG/MTN Collaborations

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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