GSK - HIV Collaborative Research Trials in the resource-poor setting

Washington DC, Sept 19th, 2005

- **Background** : Information sharing
  - Unique program supporting treatment-guidelines/policy informing studies and public-health related research
- **Goals**
  - Share program remit, process & review criteria
  - Scope: key topics for the resource-limited setting
    - Key example: pMTCT
  - Identifying the issues : GSK's perspective

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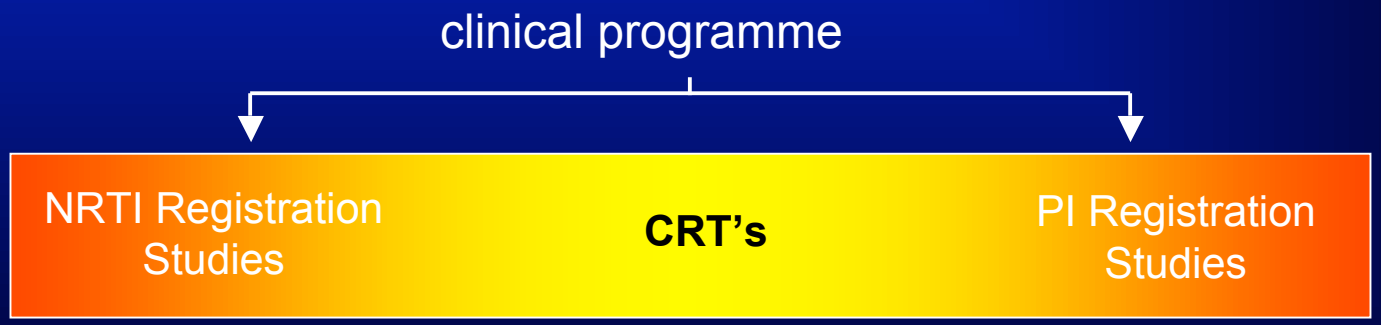
Introduction HIV – CRT's

Program Conceived 1995

- External Investigator Initiated/sponsored Studies

  = Collaborative Research Trials (CRT's)
- *Collaborations* with NIH, CDC, ANRS, WHO, MRC or individual universities
- GSK support studies with donation of drug and / or funding
- Historically committed to resource-poor setting



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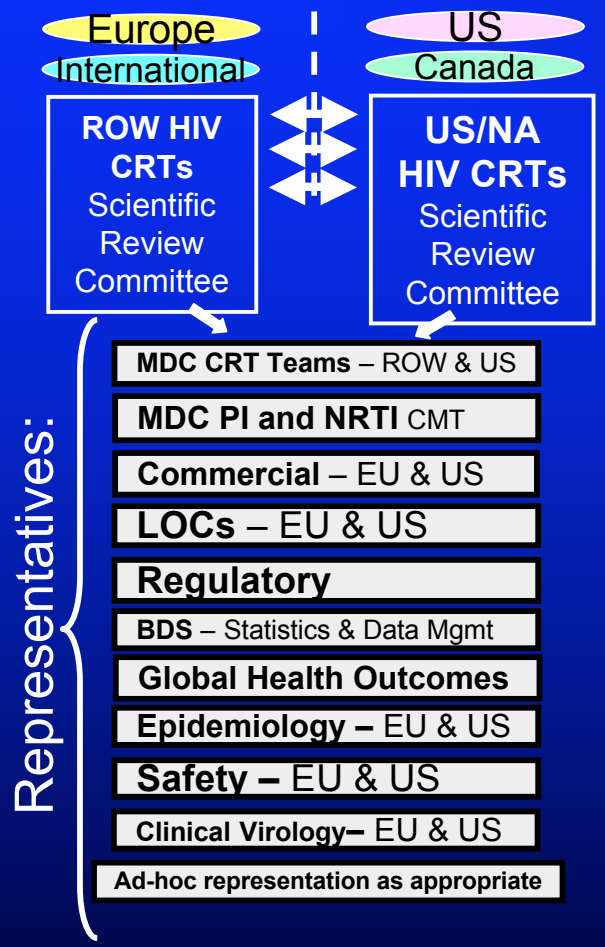
GSK Review Process



Proposals reviewed only if scientific information is complete

General Approval Criteria

- Scientifically and ethically sound
- Focus on patient safety
- Committed post-study care and medication (mandatory)
- Credible research groups / investigator
- Must have viable infrastructure supported by third parties

Qualification for Funding: must address

- Question relevant to resource poor setting
- Support trials that are policy informing
- Public health relevant research
- Novel scientific question, clear scientific data gap
- Complementary to existing commitments (avoid duplication)

Consider:

- Geographical distribution
- Fair spread between different organisations / networks
- Capacity building / technology transfer

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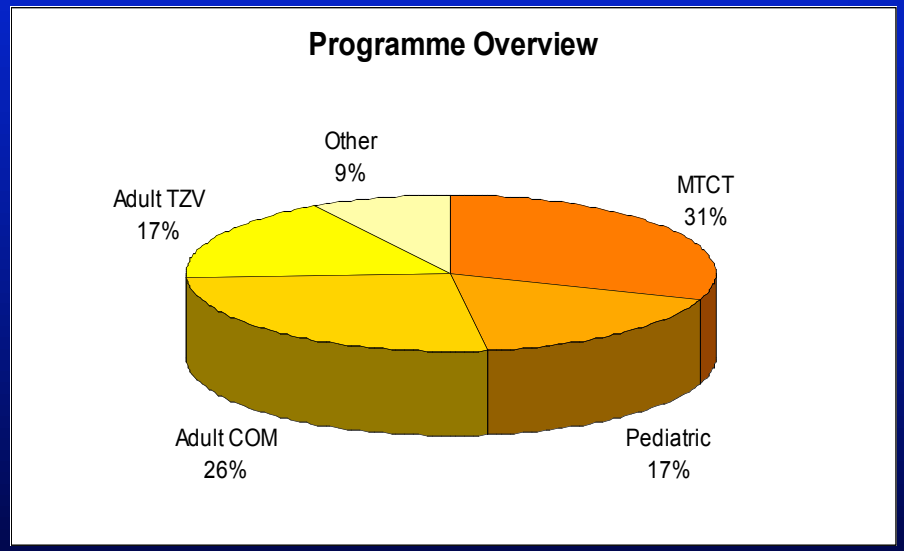
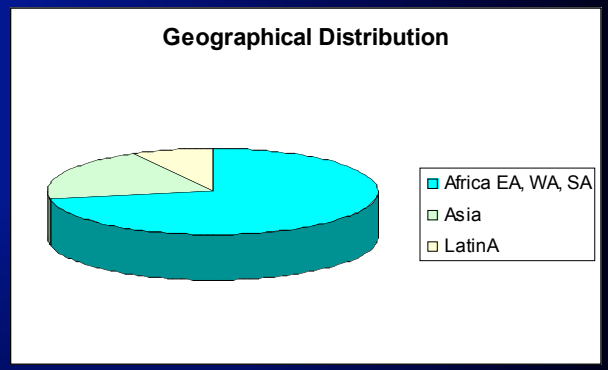
What is GSK currently doing?

- Support 26 policy-informing clinical studies in resource poor setting
- GSK donates study drug (and/or financial support) and provides scientific input

16,500 patients





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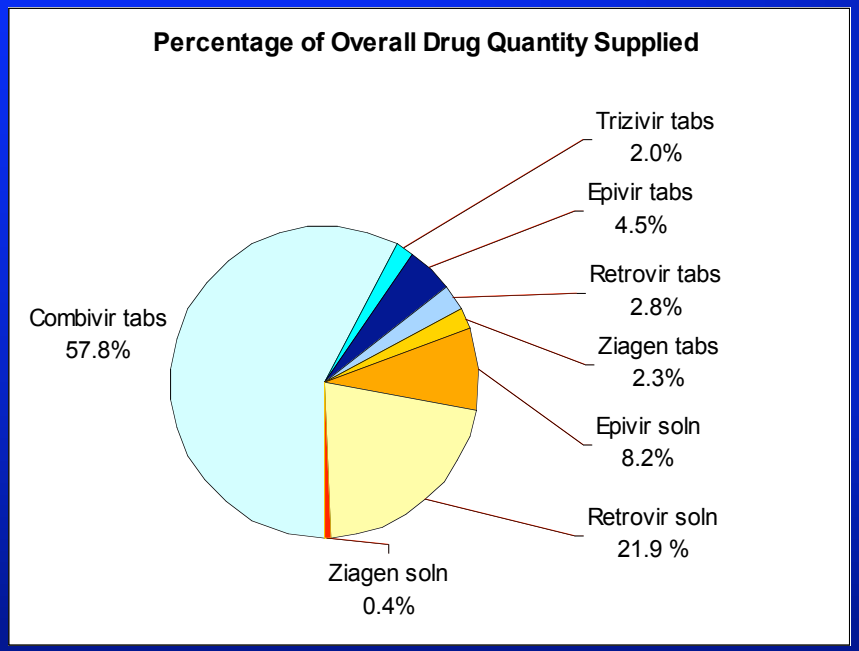
What does support of 26 studies mean?



- On average, GSK donates 66% of CTM required for these studies
- Study duration ranges from 3 to 260 weeks
- Recruitment periods range up to 104 weeks - for some medication provided until last-patient-last-visit
- 60- 80 % off commitment towards CBV

Approx 16,500 patients = 36,000 patient years of drug donation

- = $7,684,000 at NFP price

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Unmet Medical Needs

- Prevention of Mother-to-Child-Transmission (pMTCT)
- Treatment Strategies in HIV-TB co-infection
- Paediatric Treatment Strategies
- Treatment Monitoring Strategies
- Horizontal HIV Transmission Prevention
- Treatment Guidelines (WHO)

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GSK Participation in MTCT Studies

- Long history of supporting MTCT studies with studies influencing both local and International guidelines:
  - 11/ 15 studies in reference Table 1 on WHO guidelines were GSK supported

- 6 MTCT studies in Africa & Asia have/are about to report data:
  - PHPTII: N Eng J Med 351:217-228 and 229-240 (2004)
  - PETRA: IAS 2003, ICASA2003, Lancet 2004
  - SIMBA: IAS2003 (LB), ICASA2003 (LB), IAC2004 (LB), CROI 2005, submitted Nature Medicine
  - DITRAME-Plus: IAS2003 (LB), ICASA2003, CROI 2004, CROI 2005 (LB)
  - MITRA. IAS2005
  - MASHI: IAS2003, ICASA2003 (x2), IAC2004 (x3), CROI 2005 (2x LB), JID 2005 (2x), submitted NEJM

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Challenges Supporting Research in Resource Limited Settings – GSK Perspective

- Full collaboration – drug donation – areas for improvement
  - Decision making transparency within research groups
  - Planning ahead
  - Coordination between 'competing' research networks
  - Reliable study start predictions
  - Improved feasibility studies - impacts of study delays
- Challenges NFP provision: different stakeholders & sourcing routes
  - Lack of familiarity of all parties with process: challenges with trading terms / conditions (e.g.; freight charges, import duties, import licence),
  - Increased amount and complex interfaces – communication challenges
  - In-house / external processes may not be optimally in-lined.
  - Complex Local Regulatory environment (s) – not all products / presentations registered & significant differences between country

<u>Strong collaborative PARTNERSHIP CRITICAL</u>

- Researchers, sponsor, local communities and health policy makers
- Increasing scrutiny and accountability of industry !

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