

MTN 020

Qualitative Component:

Update

Ariane van der Straten, PhD, MPH

BRWG representative

Women's Global Health Imperative

RTI International

San Francisco, CA, USA

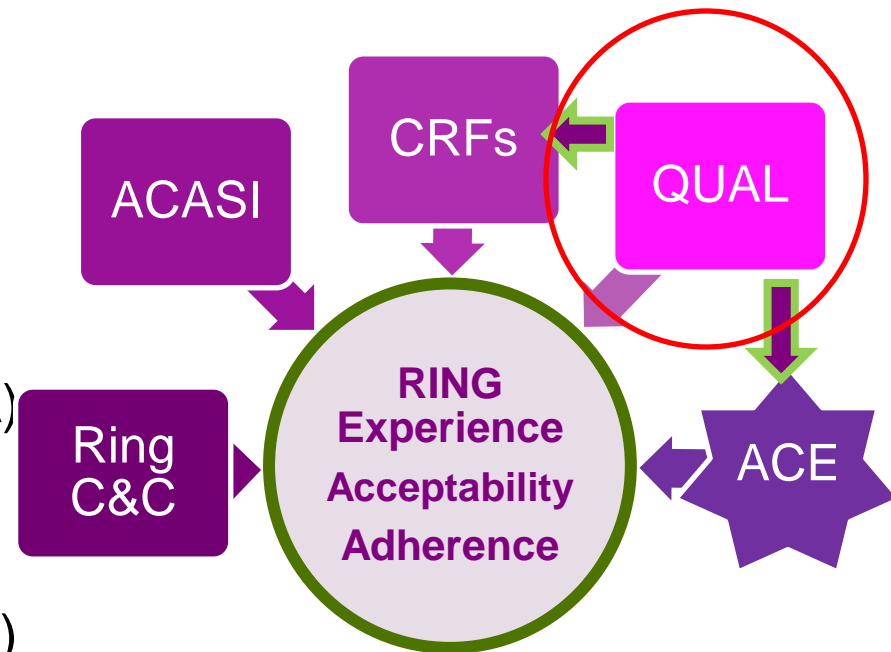


Purpose and Rationale

- To collect in-depth contextual data on ring use-experience, acceptability & adherence
 - Data collected en-route & at study's end
- To complement ACASI and CRF data
- To offer insights into trial results and potential future use of ring in non-trial settings

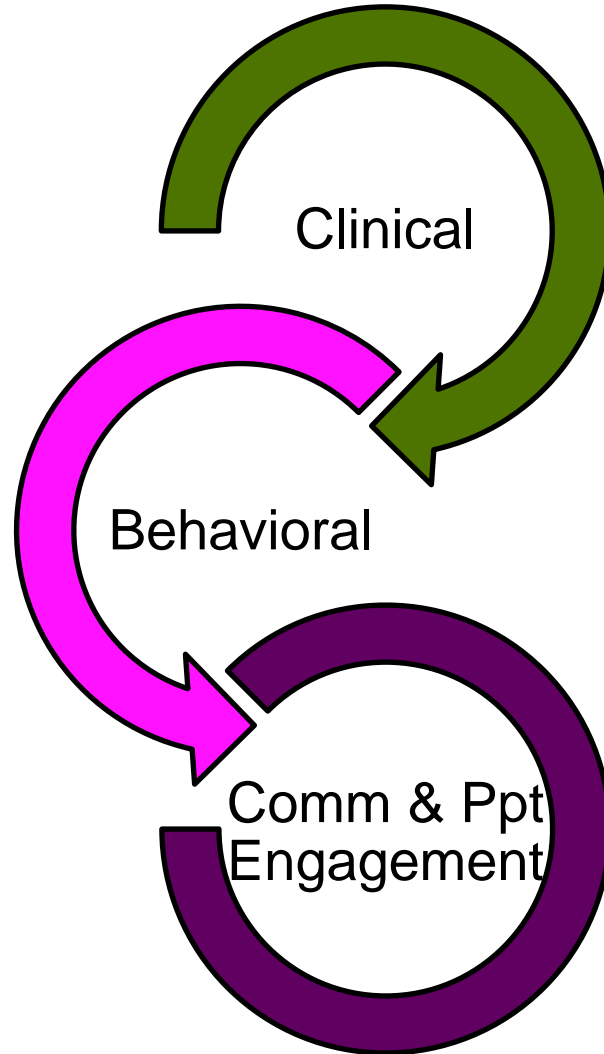
ASPIRE Behavioral Measurements & Activities

- Ring counts & collection
 - Accountability, visual inspection, residual drug testing, (biofilm)
- ACASI (Bas, M3, PUEV)
 - Sensitive sex questions (anal sex)
 - Vaginal practices (detailed)
 - Ring acceptability
 - Expulsions/removals, reasons
- CRFs; FTFI
 - Menstrual/vaginal practices (B, SA)
 - Ring adherence (M)
 - Ring worries/concerns (B, M3, P)
 - Main partner/sexual behavior (B,Q)
- **Qualitative Component (M3, M12, P)**



All parts are working together....

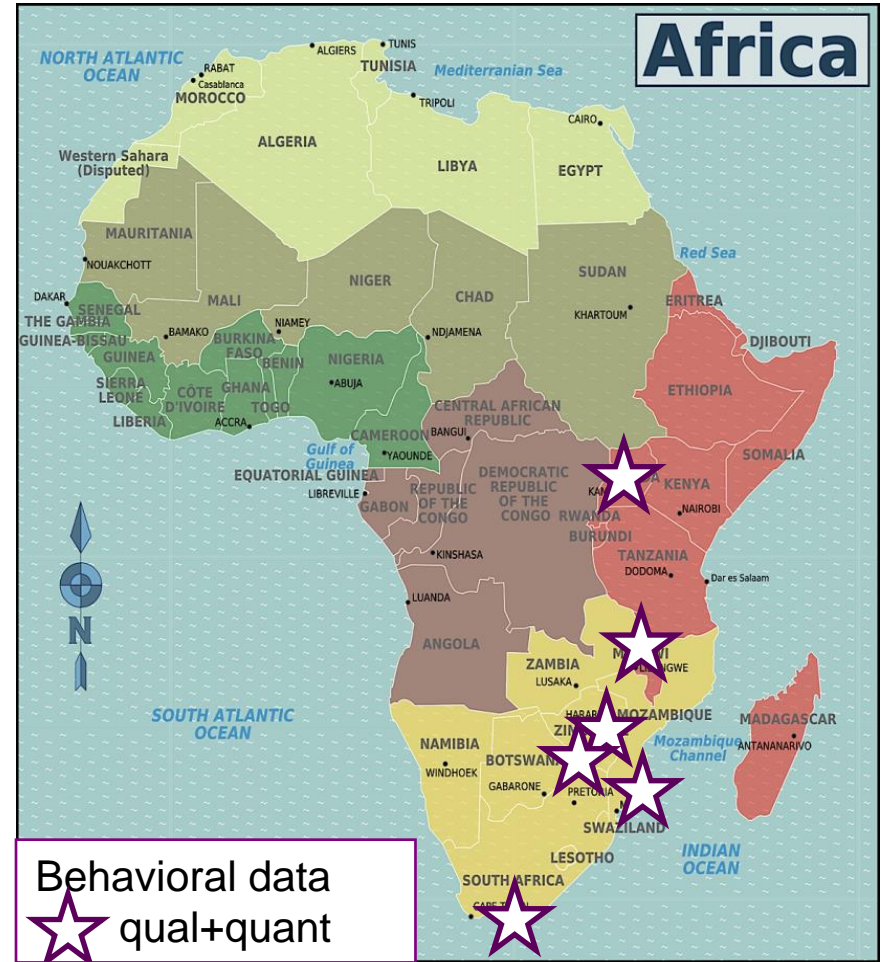
- **Within sites**
- **Across sites**



Locations

6 CRS / 4 countries

- **MU-JHU** (Kampala, Uganda)
- **Spilhaus** (Harare, Zimbabwe)
- **UNC** (Lilongwe, Malawi)
- **Wits RHI** (Johannesburg, RSA)
- **DTHF** (Cape Town, RSA)
- **MRC/Isipingo** (Durban, RSA)



Methods:

Combination of types of interviews

- Serial IDIs
 - Women randomly selected at each site
2-3 SIDIs: Month 3, Month 12 and/or PUEV
 - A couple of women are purposively selected (special cases) by site & management team
- Single IDIs:
 - Premature product discontinuation (e.g. seroconversions, early terminations)
- Exit FGDs
 - ~2 groups per site

Sample size per site:

| Type of Qualitative Data Collection | # of women per site | # of interviews/ FGD per site |
|-------------------------------------|---------------------|-------------------------------|
| Serial IDI | ~12-14* | 24-42 |
| Premature termination IDI | ≥3** | 3 |
| FGD | 20 | 2 |
| Total | ~35 | ~29 - 47 |

(*) of those, up to 2 can be purposively selected by site staff

(**) a minimum of 3 premature terminators - and up to a maximum of all seroconverters, at a given site.

Topics of Special Interest: IDI

- Ring **acceptability**, willingness to use in future
- Adherence to ring use, **challenges** to use
- Role of **clinic environment/counseling** on ring use
- **Partner** disclosure, influence and attitudes
- **Sexual** behavior, including anal sex
- **Motivation** to join the trial & **HIV risk perception**
- Effect of **menses** on ring use
- **Impact** of ring use on **sexual** activity, sexual **pleasure**, **condom** use, and **intravaginal** practices
- **Change over time** (serial interviews)
- **Special issues** for case studies, (i.e. circumstances & timing of seroconversion or early study/ product termination, etc.)

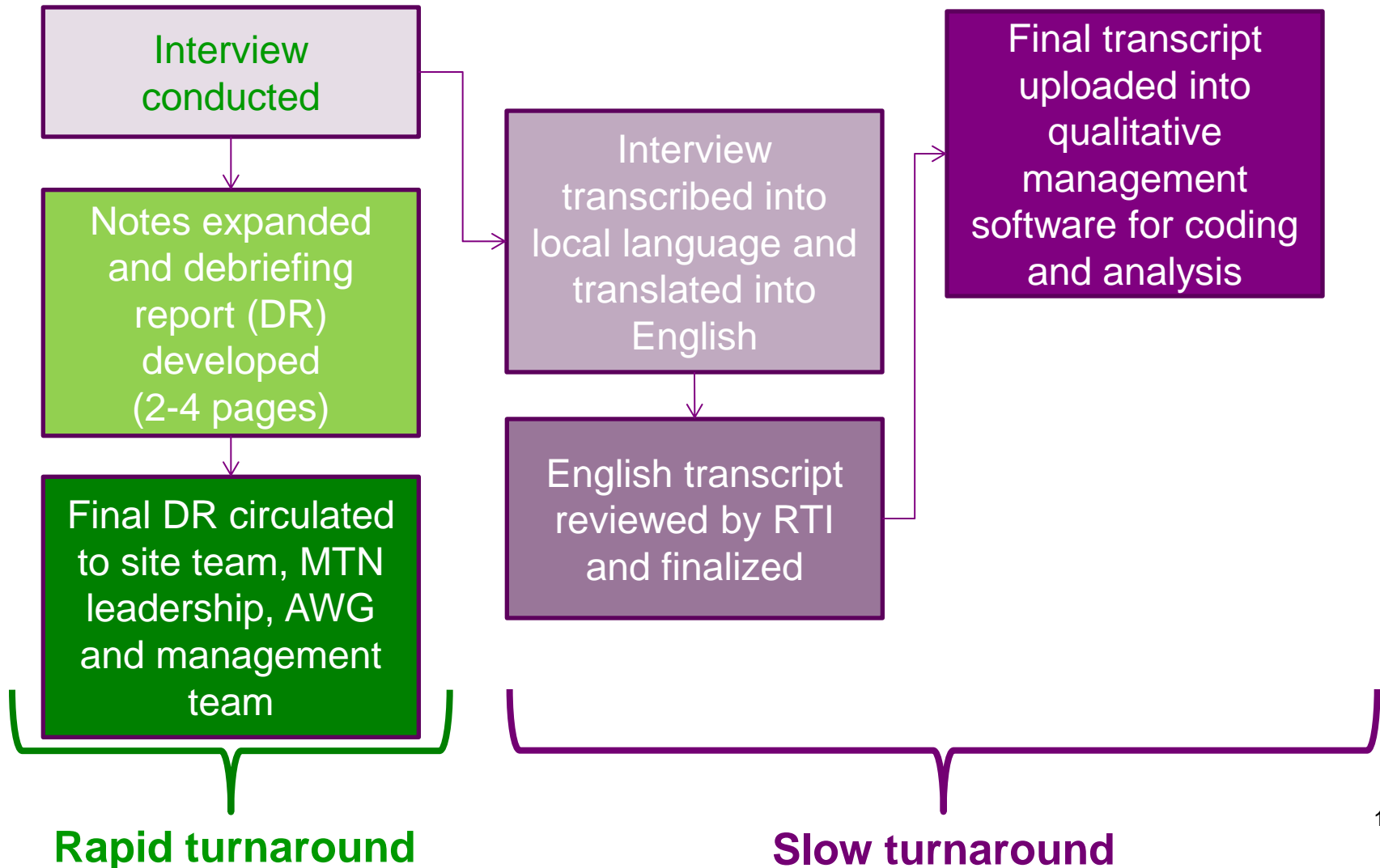


Topics of Special Interest: FGD

- **Community's** perspective on HIV, RCT and ASPIRE
- **Motivations** to join the trial
- **Disclosure** and influence of others
- **Experience** in ASPIRE (incl. ppt engagement activities)
- **Experience** with the ring (incl. male partner's views)
- **Feasibility** for future use
- **Recommendations** about ring and the trial

- **Contingent questions** if change in trial design/early stopping take place (ready to implement)

Data Management



020 Qual update (as of Oct 21)

| Site | No. Participants Interviewed | | | | Total Interviews | Total Interviewed | No. Debriefing Reports Complete | No. Transcripts Complete |
|--------------------|------------------------------|----------|----------|------------|------------------|-------------------|---------------------------------|--------------------------|
| | Serial IDI | | | Single IDI | | | | |
| | SIDI 1 | SIDI 2 | SIDI 3 | | | | | |
| DTHF | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MRC (Isipingo) | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 |
| Wits RHI | 6 | 0 | 0 | 1 | 7 | 7 | 4 | 0 |
| MU-JHU | 12 | 6 | 0 | 1 | 19 | 13 | 18 | 7 |
| UZ-UCSF (Spilhaus) | 12 | 1 | 0 | 2 | 15 | 14 | 15 | 14 |
| UNC-Lilongwe | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 31 | 7 | 0 | 4 | 42 | 35 | 37 | 21 |



QUESTIONS?
