



VOICE in Zimbabwe:

VAGINAL + ORAL INTERVENTIONS
TO CONTROL THE EPIDEMIC

The road to activation

Nyaradzo Mgodi for The Zimbabwe Team
MTN Regional Meeting, Cape Town
20 Oct 2009

IRBs/DRAAs

- ZNFPC, Chitungwiza City Health Dept and JREC
- MRCZ
- CHR
- MCAZ
- RCZ
- PRO-RCC, DAIDS

MRCZ

- 01 Oct 08 – initial submission
- 27 Jan 09 – first review
- Resubmission – 11 Mar 09
- Approval – 26 Mar 09
- 08 Apr 09 – CHR request, resubmission to MRCZ – new issues
- 11 Jun 09 – re-submitted ICFs
- 25 Jun 09 – ICF approved, recruitment materials approved.

CHR

- 02 Dec 08 – Initial submission
- 22 Jan 09 – 1st review
- March 2009 - response
- 08 Apr 09 – conditional approval
- 18 Jun 09 - approval.

MCAZ . . .

- 01 Oct 09 – initial application
- 27 Jan 09- 1st review
- Feb 09 – 2nd submission
- 26 Feb 09 – 2nd review
- Mar 09 – FDA IND approval submitted
- 24 Mar 09 – committee recommends VOICE to secretary for Health.
- 30 Mar – GMP certificate and certificate of analysis.

...MCAZ

- 30 Apr 09 – submitted shelf life claim and data
- 18 May 09 – approval
- Application to import phosphate supplements 28 May, approved 08 June
- Application to import study product on 03 June, approved 08 June

PRO - RCC

- 26 May 09 – initial submission
- 29 May 09 – submission of additional materials requested – CHR approval
- 09 Jun 09 – initial approval notification of English ICFs
- Shona ICFs approved – 11 Aug 09

On-site preparations

- Preparatory activities
- Training: 9-17 July 09
- Pharmacy: Pharmacy Establishment Plan and PAB approval - 17 Aug 09
- Laboratory: MTN NL approval - 20 Aug 09
- Data: SDMC approval on 21 Aug 09
- Study specific SOPs, visit checklists, staff roster and organogram - 26 Aug 09

DAIDS

- 27 Aug 09 – Spilhaus activated
 - ❖ Already had participants for screening

- 02 Oct 09 – Seke South activated

What else worked well?

- Translations of materials – helped with protocol understanding
- Different teams with specific roles
- Pre-FHI on-site training
- Role plays
- Walk-through
- Staggering of activation and implementation

Study Progress . . .

1st month; 14 Sep-13 Oct:

- 52 women screened, 10 enrolled
- 6 oral arm, 4 vaginal arm
- Average age: 28.3 years
- 10 (19.2%) screened out due to HIV positivity
- 1 (1.9%) screened out due to HBV positivity
- 3 (5.8%) screened out due to pregnancy
- 6 (11.5%) screened out due to other reasons
- Commonest STI: Trichomoniasis

. . . Study Progress

M1 follow-up; 12 Oct 09:

- Experienced nausea first four days only
- Adherence good, one missed dose

Seke South:

- 17 women screened, 13 eligible thus far.
- Reasons for screening out:
 - ❖ Pregnancy-2, rural location and need to have a baby in the next 24 months

...Study Progress

PPD monitoring 12-16 Oct 2009

- ❖ Regulatory binders
- ❖ Participant binders
- ❖ Pharmacy issues

Thank you to:

- Protocol team for their leadership
- NIH for their support
- CABs for their commitment
- Site staff for hard-work
- Gilead and Conrad for study product
- You all for listening