

### The road to activation

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





### IRBs/DRAs

- 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 1<sup>st</sup> 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 2<sup>nd</sup> submission
- □ 26 Feb 09 2<sup>nd</sup> review
- Mar 09 FDA IND approval submitted
- 24 Mar 09 committee recommends
  VOICE to secretary for Health.
- 30 Mar GMP certificate and



CE 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

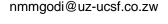
- 26 May 09 initial submission
- 29 May 09 submission of additional materials requested – CHR approval
- 09 Jun 09 initial approval notification of English ICFs
- Shona ICFs approved 11 Aug 09





## **On-site preparations**

- Preparatory activities
- Training: 9-17 July 09
- Pharmacy: Pharmacy Establishment Plan and PAB approval - 17Aug 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: 28.3years
- □ 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



