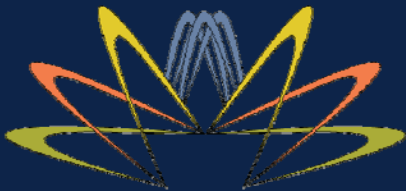


dfnet  
research

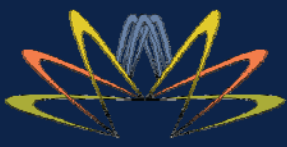
presents



South Africa  
**DFUG 2016**

**Generating Study Site Monitoring Reports  
and Reconciling Study/Lab Data**

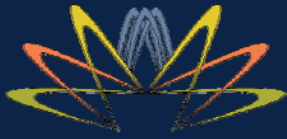
Perinatal HIV Research Unit, Soweto, Johannesburg, South Africa  
Nick Moodley, Joseph Makhura, Yudesh Baliram



## INTRODUCTION Perinatal HIV Research Unit (PHRU)

---

- Chris Hani Baragwanath Hospital in Soweto, JHB; Satellite sites
- Networks – IMPAACT, ACTG, HVTN, HPTN
- Paediatric/Adult pharma trials
- 2002/2003 - DataFax installed, Statistics & Data Management Centre opened (CIPRA-SA)
- PI driven studies – HIV/TB, Adolescent/Adult/Household surveys
- External clients – IAVI, FACTS, CIPRA-SN, etc.
- Scheduled QC and Monitoring reports generated across all studies
- Standard DataFax reports, SAS, Excel (graphs)



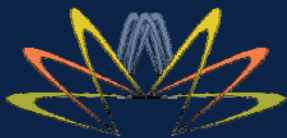
## REPORTS

---

The figures and reports in this presentation are based on **FACTS-001 datasets** (Tenofovir Gel Microbicide HIV prevention trial)

*(A Phase III, Multi-Centre, Randomised Controlled Trial to Assess the Safety and Effectiveness of the Vaginal Microbicide 1% Tenofovir Gel in the Prevention of Human Immunodeficiency Virus Type 1 Infection in Women ).*

The study had enrolled **2059** participants who attended monthly visits and had processed over **736 000** faxed CRF pages over **~3 years**.



## REPORTS cont.

---

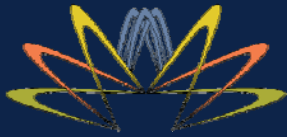
**The following reports were generated during the study:**

- **Regular study site monitoring reports**

*(requirements were provided by the **FACTS CORE** team)*

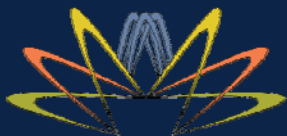
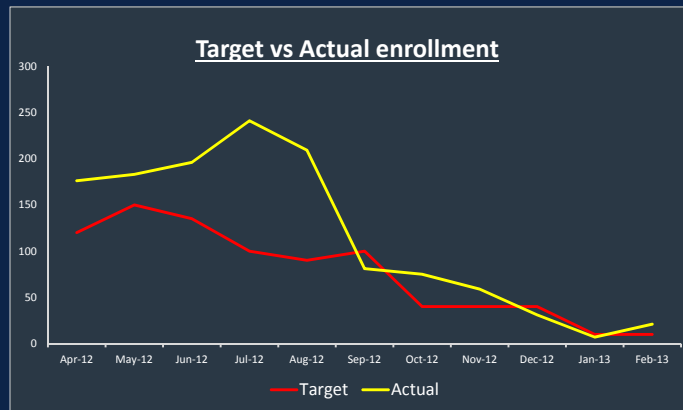
- **Ad-hoc study reports**

*(Reports that were not developed as part of the regular set, but were requested as necessary to gauge aspects of study/site performance as issues arose)*



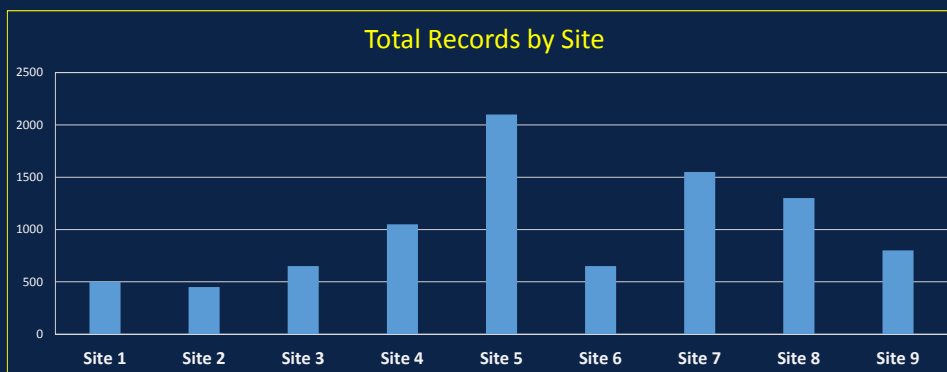
## Regular reports

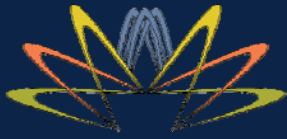
### 1. Participant enrolment (*Target vs Actual*)



## Regular reports cont.

### 2. Total number of records faxed by each site

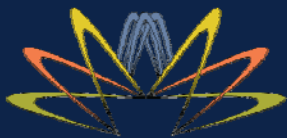




## Regular reports cont.

3. Missed visit summary report - indicates the number of consecutive visits missed

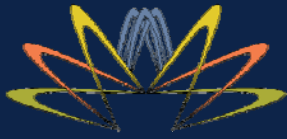
Site	Total	Missed > 5 Consecutive Visits	Missed 5 Consecutive Visits	Missed 4 Consecutive Visits	Missed 3 Consecutive Visits	Missed 2 Consecutive Visits	Missed 1 Visit
SITE 1	25	15	1	0	3	2	4
SITE 2	64	40	2	4	4	4	10
SITE 3	54	23	8	5	5	2	11
SITE 4	45	20	1	11	3	1	9
SITE 5	31	15	2	1	5	2	6



## Regular reports cont.

4. The retention report below shows the number of visits expected vs number of visits completed

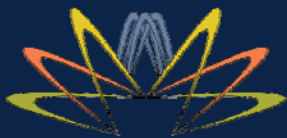
Site	Month No.	Expected	Completed Visit	Inside WP	Interim	Missed	Terminated	Overdue	Retention Rate
SITE 1	Month 1	181	149	0	12	17	3	0	89
SITE 1	Month 2	178	143	0	7	26	2	0	84
SITE 1	Month 3	175	139	0	9	26	1	0	85
SITE 1	Month 4	174	133	0	8	33	0	0	81
SITE 1	Month 5	174	129	0	13	31	1	0	82
SITE 1	Month 6	173	123	0	11	35	4	0	77
SITE 1	Month 7	169	121	0	9	36	3	0	77



## Regular reports cont.

5. The following QC status report was generated using reports/calculations within DataFax

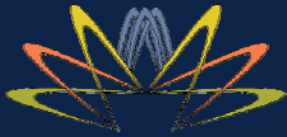
Site	Total Records	QC Total	QCs resolved	% of QCs resolved	QC rate per100	Mean Days To Fax	Mean Days To Fax AE	Mean Days To Fax ConMed	Mean Days To Fax Preg	QCs < 30d	QCs 30to60d	QCs > 60d
<b>SITE 1</b>	1184	25	12	48	2	3.4	4.7	None	None	1	0	0
<b>SITE 2</b>	1936	85	49	58	3	2.0	2.0	None	1.0	7	0	0
<b>SITE 3</b>	5073	155	52	34	3	1.9	2.3	2.0	2.0	32	0	0
<b>SITE 4</b>	2083	103	52	50	5	3.0	6.7	4.3	4.0	8	0	0
<b>SITE 5</b>	1644	94	45	48	5	3.3	0.3	0.7	0.5	15	0	0
<b>SITE 6</b>	1888	67	39	58	3	5.1	0.9	None	None	4	0	0
<b>SITE 7</b>	903	31	11	35	4	1.4	1.1	None	None	2	0	0



## Regular reports cont.

6. Termination report highlights the number of terminations and reasons per site

Termination Reason	SITE 1	SITE 2	SITE 3	SITE 4	SITE 5	SITE 6	SITE 7	SITE 8	SITE 9	Total
End of Study	10	20	13	2	0	8	50	0	0	103
Lost to follow-up	0	0	2	0	0	0	1	0	0	3
Participant refused further participation	14	29	24	16	29	23	9	30	5	179
Investigator decision	0	0	2	2	4	1	0	0	2	11
Inappropriate enrollment	0	0	0	0	0	0	0	0	0	0
Early Study Closure	0	0	0	0	0	0	0	0	0	0
Death	0	0	1	1	1	0	0	2	0	5
Participant relocated and no follow-up planned	0	1	8	1	2	5	8	11	0	36
Other	1	10	26	3	7	21	1	1	10	80
<b>Total</b>	<b>25</b>	<b>60</b>	<b>76</b>	<b>25</b>	<b>43</b>	<b>58</b>	<b>69</b>	<b>44</b>	<b>17</b>	<b>417</b>

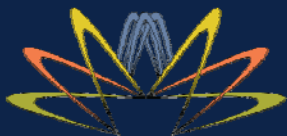


## Regular reports cont.

### 7. Missed Consecutive visits:

Helped the sites to identify problematic participants before they became serial defaulters by generating the report below

PID	ENR	M1	M2	M3	M4	M5
900017	21OCT2011 (Complete-1)	16NOV2011 (Complete-10)	13DEC2011 (Complete-20)	13JAN2012 (MV-30)	10FEB2012 (MV-40)	09MAR2012 (MV-50)
900039	24OCT2011 (Complete-1)	23NOV2011 (Complete-10)	29DEC2011 (Complete-20)	16JAN2012 (MV-30)	13FEB2012 (MV-40)	12MAR2012 (MV-50)
900042	31OCT2011 (Complete-1)	28NOV2011 (Complete-10)	26DEC2011 (MV-20)	23JAN2012 (MV-30)	20FEB2012 (MV-40)	19MAR2012 (MV-50)
900109	28OCT2011 (Complete-1)	25NOV2011 (Complete-10)	19DEC2011 (Complete-20)	20JAN2012 (MV-30)	16FEB2012 (Complete-40)	16MAR2012 (MV-50)
900153	10NOV2011 (Complete-1)	08DEC2011 (MV-10)	05JAN2012 (MV-20)	02FEB2012 (MV-30)	01MAR2012 (MV-40)	29MAR2012 (MV-50)
900182	14NOV2011 (Complete-1)	13DEC2011 (Complete-10)	20JAN2012 (Complete-20)	07FEB2012 (Complete-30)	05MAR2012 (MV-40)	02APR2012 (MV-50)

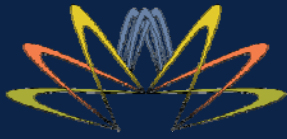


## Regular reports cont.

### 8. Unresolved AE listing.

Since there were Site Liaison Officers at **CORE**, we ensured that a regular listing of unresolved AEs was generated frequently, which they then communicated with each site about

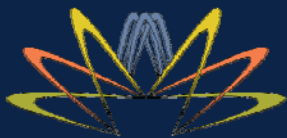
PTID	Visit Date	Page no	AE Description	Onset Date	Status	Outcome Date
900001	21 November 2012	02	EPIGASTRIC PAIN	07 November 2012	Continuing	
900002	14 August 2014	02	LOW PHOSPHATE	08 August 2014	Blank	
900003	13 February 2014	01	AMENORRHOEA	01 June 2012	Continuing	
900004	18 June 2014	14	ELEVATED ALT	24 April 2014	Continuing	
900005	21 September 2012	03	AMENORRHEA	19 September 2012	Continuing	
900006	15 August 2012	01	AMENORRHOEA	07 August 2012	Continuing	
900007	08 November 2013	09	VAGINAL DISCHARGE SYNDROME		Continuing	
900008	19 April 2013	03	ANAEMIA	17 April 2013	Continuing	
900009	20 September 2012	01	PROTEINURIA 1+	20 September 2012	Continuing	
900010	13 March 2013	02	ELEVATED AST	11 March 2013	Continuing	



## Regular reports cont.

### 9. Reports for all repeating queries per site

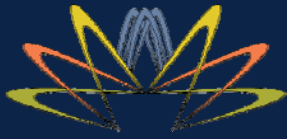
SITE	Site Queries (Frequency of queries for all open QCs)								
	Repeated 2	Repeated 3	Repeated 4	Repeated 6	Repeated 7	Repeated 8	Repeated 9	Repeated 11	Repeated 18
Site 1	8								
Site 2	16	1							
Site 3	48								1
Site 4	12		1	2	1		1		
Site 5	4							1	
Site 6	5				1	1			
Site 7	7								
Site 8	3								
Site 9	20								



## Regular reports cont.

### 10. Other regular reports:

- HIV listings (New infections)
- Summary of AE's (By severity/relatedness to study product)
- SAE listings
- Product Overdose

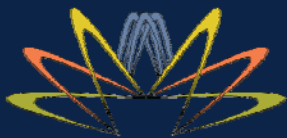


## Ad-hoc reports

---

Reports that were generated when specific issues arose during the study. These included:

- Product Inventory (Returns vs dispensed)
- Active participants (Study termination phase)



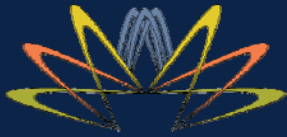
## Quality Assurance

---

In addition, performed quality assurance checks on:

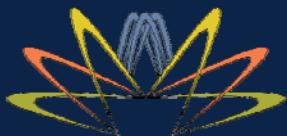
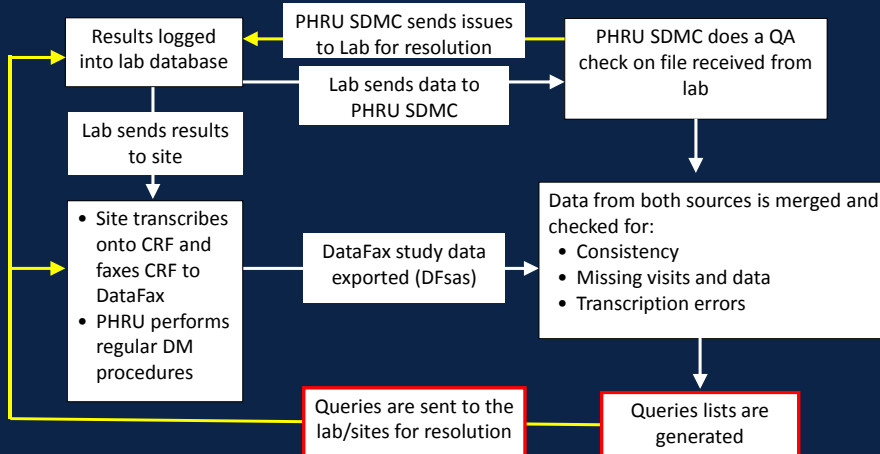
- ❖ **All critical variables, safety data and study endpoints:**
  - Adverse Events
  - Hep B results
  - Social harms
  - Product overdose
  - Terminations
  - HIV rapid and Western blot data





## Reconciling Study/Laboratory Data

Process



## Conclusion

- Various consistency checks and quality assurance can be performed during the trial and errors can be corrected throughout.
- Regular communication with site personnel also benefits these processes.
- All the above contributes to producing clean study data and speeds up database lock.

Acknowledgements

PHRU colleagues

FACTS CORE

DF Support