

Data Management Protocol: Blueprint To Stamp Good Data Management Procedures.



**Experience from a Multi-Country Study in East and
South Africa**

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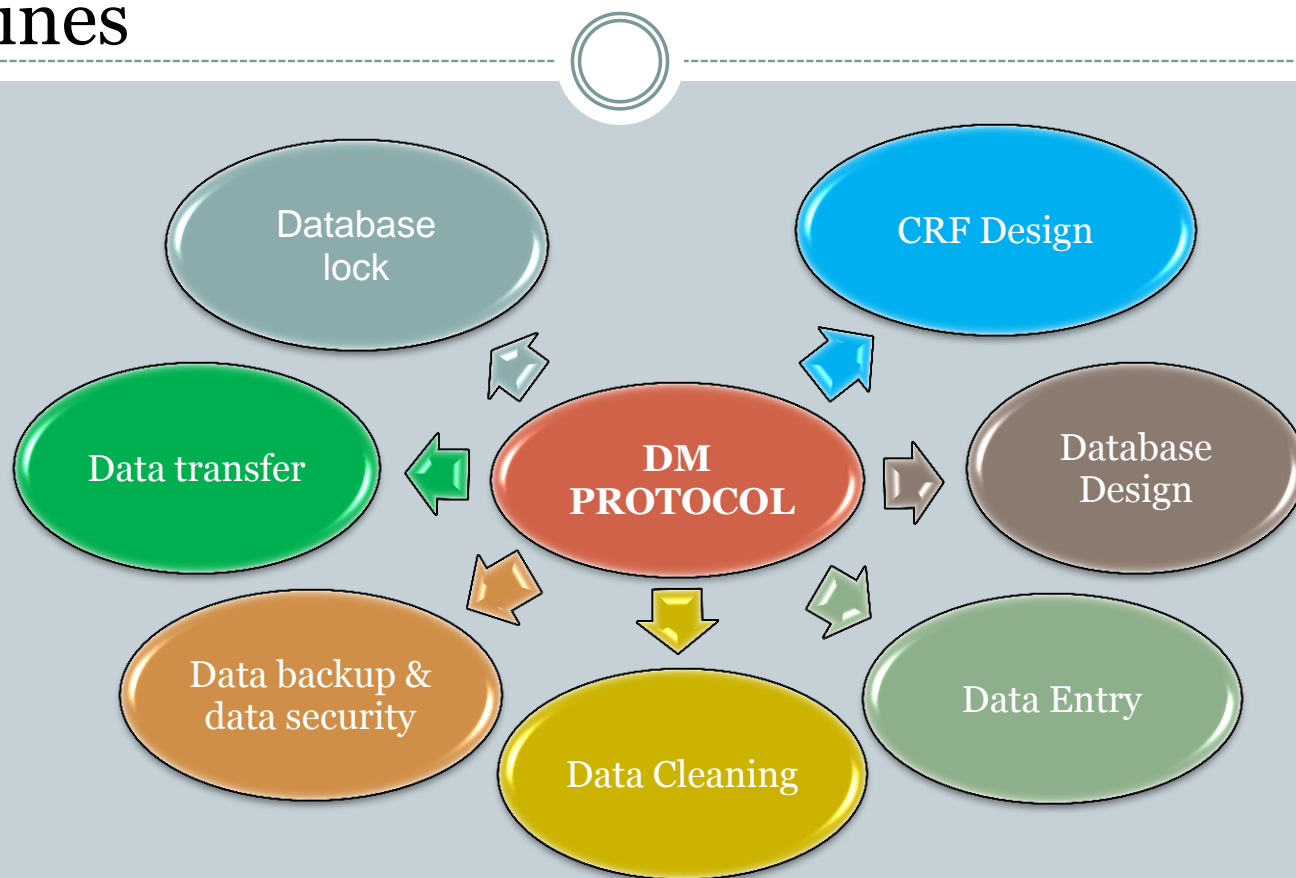
Understanding Data Management (DM) in Clinical Trials



- ❑ "Quality is never an accident; it is always the results of high intention, sincere effort, intelligent direction and skillful execution; it represents the wise choice of many alternatives". (William A Foster)
- ❑ ... 5.1.3 *"Quality control should be applied at each stage of data handling to ensure that all data are reliable and have been processed correctly"*. (ICH-GCP)

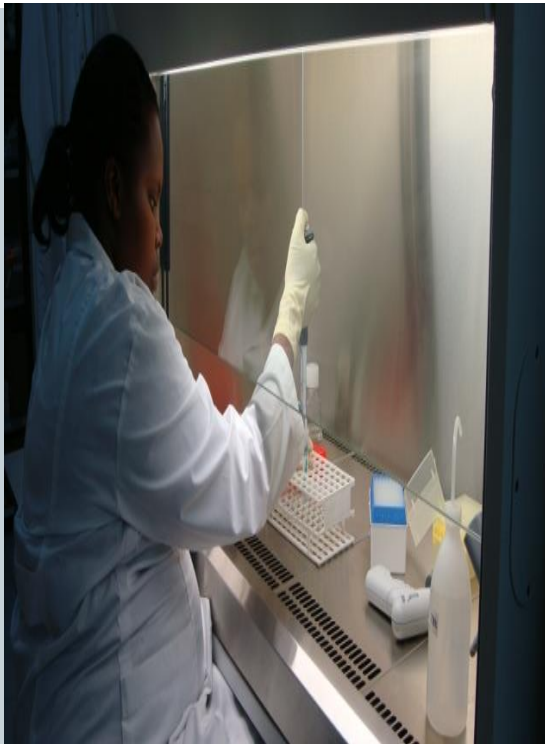
Main Elements of DMP

- Data Management (DM) process & activities
- Roles & responsibilities
- Timelines



Biomarkers Study Main Features

Study Title: Characterisation of novel microbicide safety Biomarkers in East and South Africa



Study Design: Multi-country, observational cohort study in 430 women

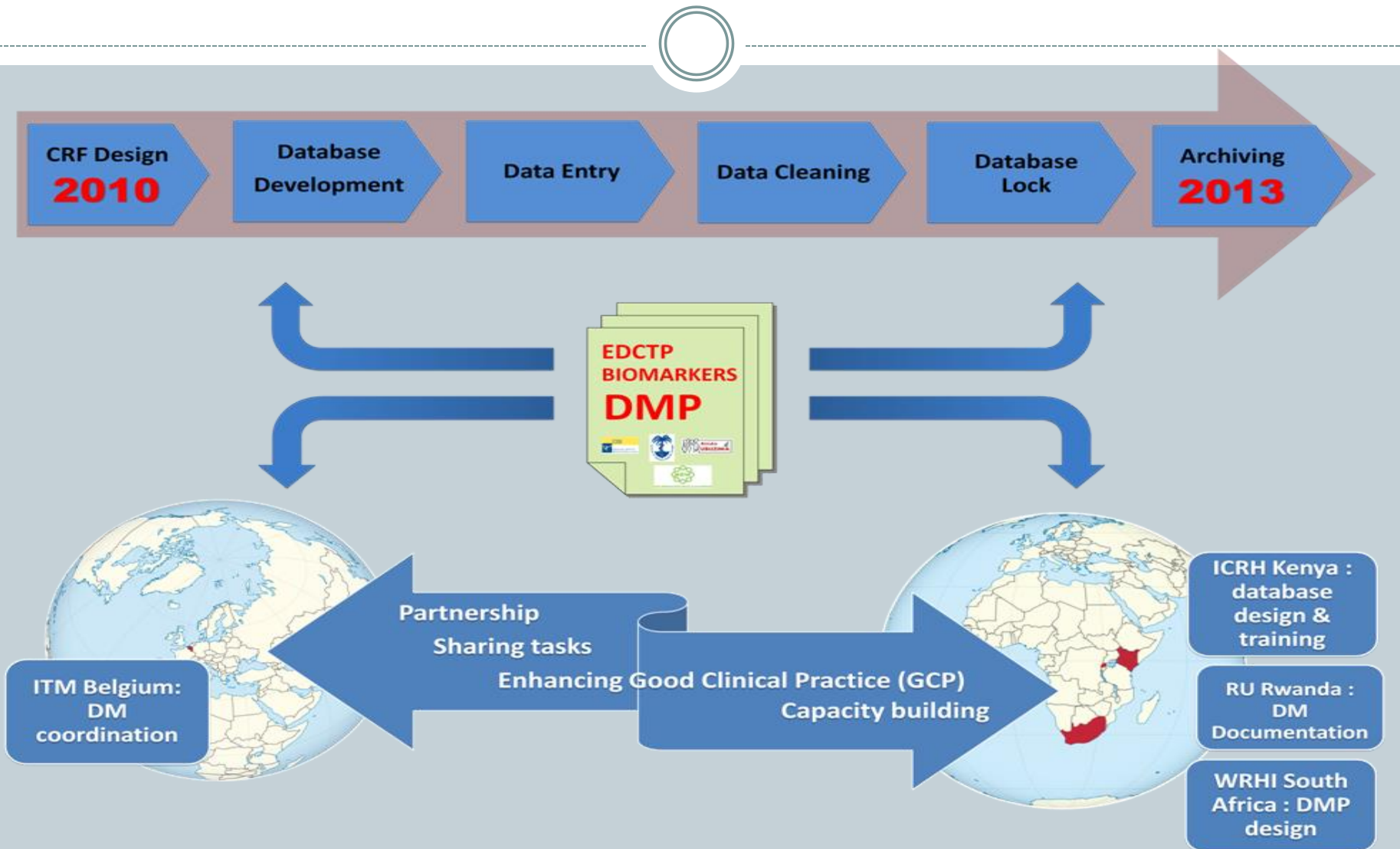
Sites:

- International Center for Reproductive Health, Mombasa, Kenya
- Rinda Ubuzima, Kigali, Rwanda
- WITS Reproductive Health and HIV Institute, Johannesburg, South Africa

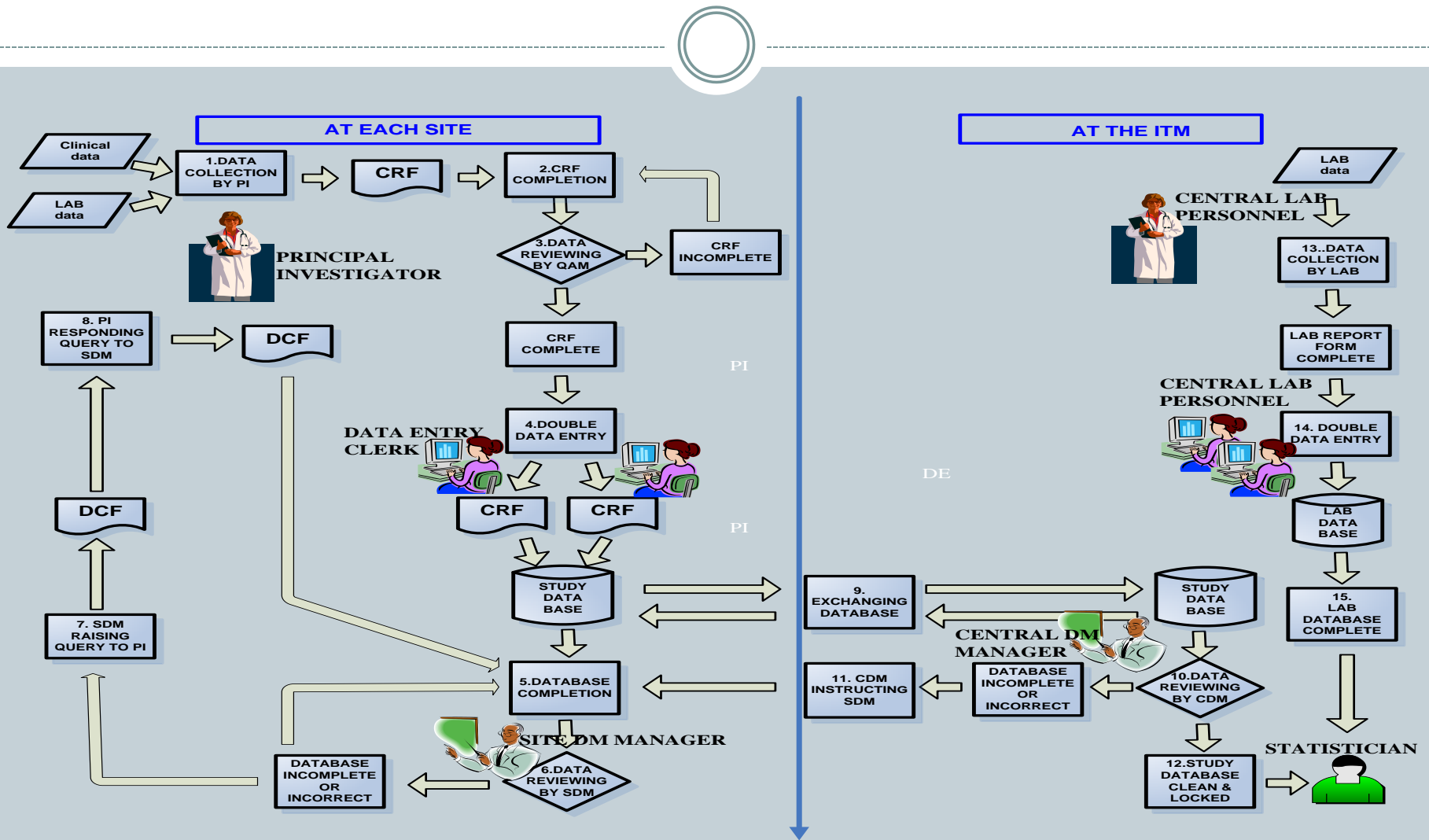
Duration: Women were followed up seven times over a period of eight months

Data Points : 2243 per study participant

Methodology



Data flow : local <> central level



Results



Adherence to DMP

- Promoted quality of DM process
- Standardized and harmonized DM process across the sites
- Ensured timely communication across the research teams resulting into coordination of key activities i.e. Data review/cleaning
- DMP became a useful reference for the monitors.

Conclusions

Trial Management



VS

Data Management



- Study protocol guides study procedures
- DMP guides the DM process
- Both are essential study documents

Networking

- Biomarkers study



'model' for

- Collaboration
- Sharing tasks
- Capacity building



- Association for Data Management in the Tropics



Workshop 2010, Belgium



Workshop 2011, Belgium



Workshop 2013, India

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- Linh Diep:** WITS Reproductive Health and HIV Institute, South Africa

Biomarkers Study Participants

