Transition to MediData Rave

MU-JHU UGANDA experience

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MTN Annual Meeting

19 March 2017

Presentation Overview

- ✓ Introduction
- ✓ Preparing for Medidata Rave
- ✓ Implementation
- ✓ Lessons Learned & Challenges
- ✓ Summary & Looking Ahead

Introduction – The demand…

- In 2016: MTN & IMPAACT networks required MediData Rave to be used for new protocols
- For MUJHU CRS pioneering studies were:
  - MTN-025 or HOPE
  - IMPAACT 1115
- MTN 025 timelines
  - Planning at annual Feb and Sep regional meetings => all sites to migrate to EDC by December 2016

Introduction – Site context…

- MU-JHU site in Kampala, Uganda has some experience with edata-management systems :
  - iDataFax
  - Cactus
  - REDCap
- medidata EDC new system from 2016
  - MTN-025 with SCHARP DMC
  - IMPAACT 1115 with FSTRF DMC
  - Other IMPAACT and HPTN 084 protocols projected for MUJHU site to use MediData Rave

A great opportunity !

- ✓ Use of medidata **represented a significant shift** from MTN paper based system with idatafax transfer used before
- ✓ We embraced it as **a great opportunity !**

Preparing for Medidata Rave

- ✓ We engaged in X-cutting and study specific planning involving:
  - – Site and study leadership
  - – IT, data, QC, QA & operations
- ✓ We established an '*eData transition taskforce*' to manage this as a priority project
  - ✓ Clear assignments and timelines were set and tracked to ensure completion on schedule

Preparing for Medidata Rave

Infrastructure

Systems

People

We considered shifts required in:

- Infrastructure
- Systems & processes
- Human resources
  - Quantitative & Qualitative

Infrastructure – Power

CHECK : RELIABLE POWER IN PLACE => no additional needs

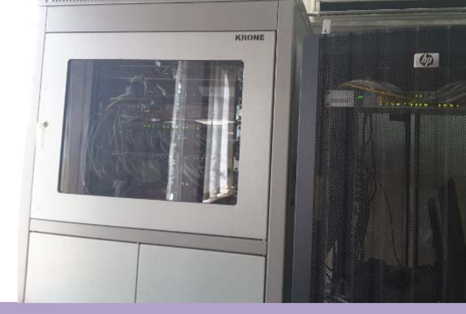
**Thanks to substantial investment with DAIDS support*

Reliable power 24/7 is required

- Main generator *(new 2015 shown)* back-up generator for critical areas
- UPS individual and for critical areas
- Emergency alarms and sensors (2015)

- Step-down transformer (March 2017)
  - *Ensures clean power and protects from surges*

Infrastructure - IT



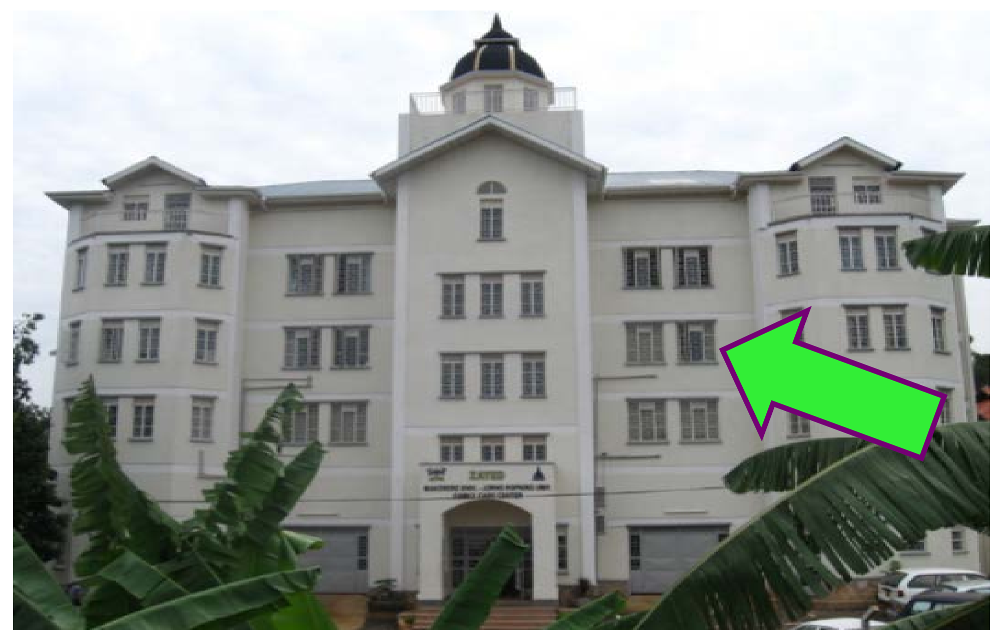
We reviewed connectivity and ICT hard/software needs to support robust and reliable connectivity and data storage

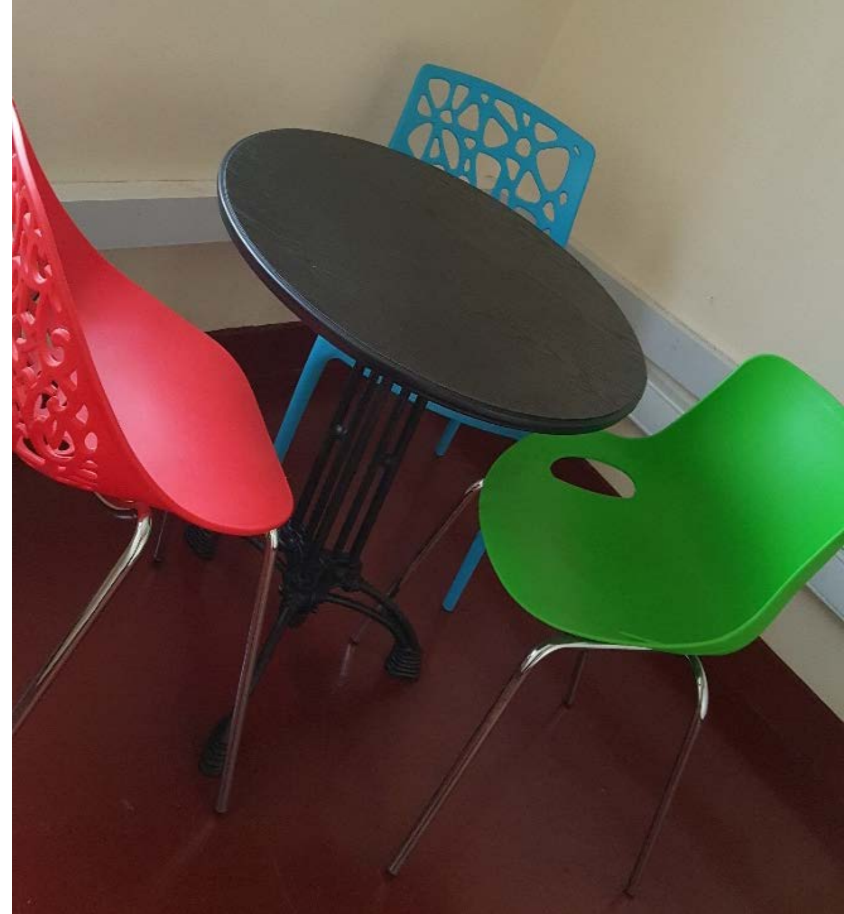
1. **Hardware needs**
   - Consultation with users & IT to define needs & specifications
     - » Considered individual or shared use, mobile or static & location
   - Procurement of desktop computers (5 Dell) & laptops (5 Lenovo)
2. **Internet connectivity and servers**
   - External links for high speed reliable connectivity
     - 10 Meg assured link with regional/continental ring for redundancy (2016) and backup link with dedicated 4 Meg
     - Capacity to rapidly increase if needed
   - Defined need and placement for more internal connections
     - Additional hard wiring to provide ethernet ports

Infrastructure – Study facilities

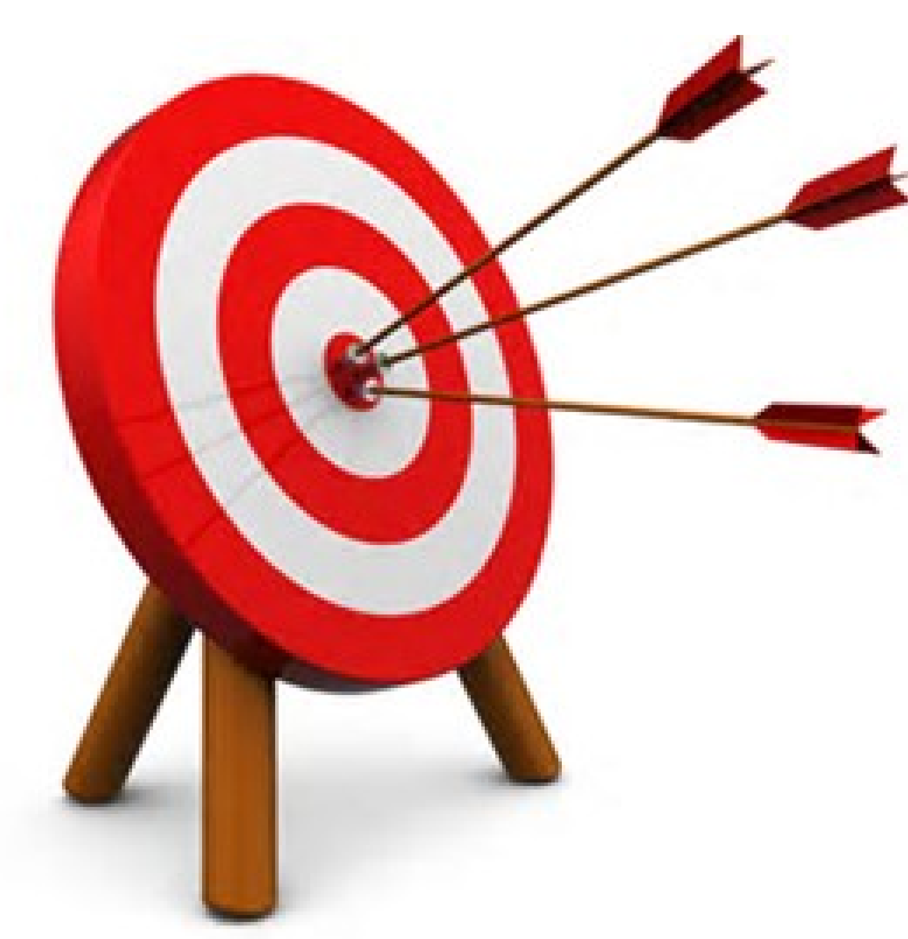
Dedicated space created for HOPE study (EDC considered)

- Initial consultation with team and renovation designed
- New counseling rooms
- Others to be completed in Q2





Infrastructure planning



Systems & Proceses

Infrastructure

Systems

People

We considered shifts required in:

- Infrastructure
- **Systems & processes**
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Data Management System

We reflected on shift from old system and processes

- ✓ **Roles – shifts in all roles:**
  - From receptionist, counselor, clinician, study coordinator, QC-1, QC-11, data entrants, data managers, records clerks to IOR
  - System generated queries requiring immediate correction eliminate many user errors
  - Requires use of computers for some cadres who had no/limited use in old system (eg QC-1, QC-11, counsellors)
- ✓ **Paper–based file** – still needed for information NOT captured
- ✓ Identified need to review and **update site CQMP** in view of EDC

CHANGE MANAGEMENT +++ is required to embrace new system

Preparing for Medidata Rave

Infrastructure

Systems

People

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The most valuable asset = people

Working together with their heads and hearts !

HOPE PoR and Study Coordinator

Site MTN Lead
Site IOR & IT
Community team and counsellors

MU-JHU HOPE & X-cutting staff

- ✓ Identified roles in relation to Medidata Rave through process mapping & definition of individual roles
- ✓ Identified individual training/support needs
  - Data team and IMPAACT 1115 team had already done e-learning course for Medidata Rave
  - Staff already proficient in computer use
  - Staff completed e-learning modules & on-site pilot testing and review of competencies
- ✓ Source Documentation SOP made clear
  - eCRFs Vs Paper CRFs
- ✓ Commitment to ongoing learning and improvement
- ✓ Team enthusiastic about using Medidata Rave +++

Medidata Rave Training…

Nurse Study Coordinator

ID#: DSO374200022313

Medidata Solutions certifies that

Joselyn Nabisere

has fulfilled all requirements to be recognized as a

Medidata Rave® Certified Clinical Research Coordinator.

October 03, 2016

Prepared for Medidata Rave !

Infrastructure

Systems

People

Implementation (1)

- Smooth implementation so far !! ☺
- MUJHU was site activated for HOPE screening and enrolment on 05 Nov 2016
  - ✓ Follow Source Doc and Data Management SOPs
  - ✓ Streamlined generation of HOPE PTIDs
    - By Data Manager only
  - ✓ CRF completion guidelines were very helpful
    - ✓ Hard copies referred to by all staff entering data

Paper CRFs

Type of Visit	Comment
Screening Visit	• Paper CRFs filled for participant screening • Visit only populates in EDS **after eligibility criteria CRF** is filled at participant enrolment • Data team enter screening visit after participant enrolls
Enrolment Visit	• Initially we had paper CRFs for all the forms filled at and after enrolment in order to gain confidence in EDC • From Jan 17 we entered directly into EDC in real time
Behavior Assessment CRFs	• English CRFs are entered directly into Medidata Rave • Delay in entry of Luganda CRF (awaiting upload - expected soon) – until then paper CRFs are entered in English into EDS after visit by data team

Non CRF source forms are paper-based: lab results forms, prescriptions, certified FP card, chart note, baseline conditions & AE follow-up form etc

Lessons Learned (1)

- ✓ It worked well to approach the transition :
  - As a site-wide priority not just as a study priority
  - Engage key users as part of a multidisciplinary team
  - Integrate change management & ongoing learning processes
- ✓ The QC resolution process was streamlined
  - Systems queries are resolved immediately by primary data collector that created them
  - QC team members responsible for resolution of manual queries with the help of staff who collected the data
    - This has resulted in fewer queries

Lessons learned (2)

- ✓ All files are a click away
  - easy to follow up on queries (manual & lab)
- ✓ SCHARP team are very helpful +++
  - Medidata migrations have made it user friendly and more streamlined *(skip patterns/prompts..)*
- ✓ Early corrective actions at weekly study meetings
  - I (Study Coordinator) shared trends of queries and correct entry for the eCRFs *(contracept, con meds etc.)*
  - Provided individualized feedback as needed
- ✓ Use of general note form was not optimal
  - Developed '*Baseline Conditions*' and '*Adverse Events Follow-up*' forms to improve documentation/tracking

Baseline Condition & AE Follow-up forms

1. Visit Date: □□/□□□/□□ (dd mmm yy)

2. Visit Month □□

List any diagnosis/es (with their grading and relationship to study product) made at this visit: (Complete AE form for all new ›ortable AEs or AEs that increase in severity/frequency)—*continue on general note if needed*

Review and comment on baseline conditions / previously reported adverse events/GAEs: □ None

licate change noted by checking the appropriate box.

- Continuing
- AE Resolved (No more follow up indicated)
- AE increased in severity (New AE; therefore complete new AE form)
- Death
- Continuing at end of study participation

verse ent mber 'A for seline)	Diagnosis	Status					Comments	New status outcome date
		0	1	2	3	4		
								□□/□□□/□□ dd mmm yy
								□□/□□□/□□ dd mmm yy
								□□/□□□/□□ dd mmm yy
								□□/□□□/□□ dd mmm yy

Lessons Learned (3)

- ✓ Change in our filing system
  - PTIDs are generated as random numbers not sequential => now file and retrieve according to 1st 6 digits
- ✓ Files with information missed on eCRFs are physically flagged for update on participant next visit
  - E.g. LNMP, con-med start/stop dates, AEs, VR tracking log last 2 questions, ring adherence
- ✓ Intermittent file review & preparing for PPD
  - Hard and e-copy to ensure consistent information and timely clean data
  - This was a priority prior to PPD monitoring visits

Lessons Learned (4)

- ✓ Streamlined clinic and data flow
  - Laptops move around rather than participants charts and participants
  - Waiting time for HOPE participants has markedly reduced compared to ASPIRE
  - Participants are amazed at the .com era in HOPE
- ✓ Printing needs is markedly reduced with small file
  - visit checklist, follow-up form, counseling documents

Challenges were minimal

- Waiting for migration of Luganda docs with work around of data entry of English forms
- Despite power planning – still had some issues with connectivity speeds
  - We sometimes fill paper CRFs/non CRF sources for this information and update Medidata Rave before COB
  - IT and admin working to address this issue…

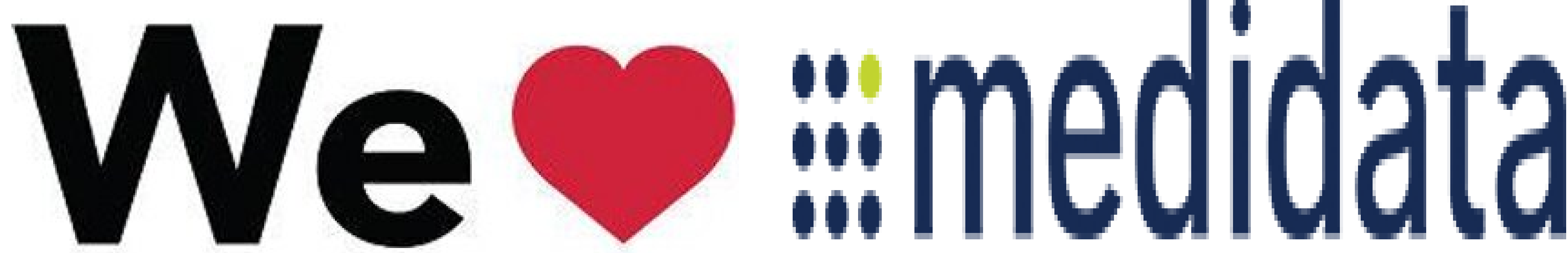
Summary

- ✓ Investment in good planning paid dividends
- ✓ Real time entry of data into Medidata Rave is simple, feasible and efficient
- ✓ QC and data entry processes shifted with reduced burden compared to prior era
- ✓ Our staff have embraced shift in roles and greater computer use (for many)
- ✓ Strong relationship and support from DMC critical to optimise study specific data management system and trouble shoot

Way forward

- ✓ Ongoing learning and sharing
- ✓ Update site CQMP integrating EDC data and QC processes
- ✓ Revisit staff needs in light of site wide adoption of EDC systems and manage staff transition
  - ✓ Project reduced need for QC-1, QC-2, data entry staff
  - ✓ Shift in staff profiles for other cadres requiring greater direct data entry and computer competencies
  - ✓ Requires greater IT investment in systems & IT support

Overall



Special thanks from the MUJHU records clerks

CARTOONSTOCK .com

"I can't wait until we convert to electronic health records. Carrying all these around is giving me a backache."

感謝你
Danke
Gracias
Grazie
Merci
Thanks!

THANK YOU!

Acknowledgements

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MTN microbicide trials network