EDC vs Paper based data collection

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About CAPRISA

Centre for the AIDS Programme of Research in South Africa

Established in 2002 under the NIH-funded Comprehensive International Program of Research on AIDS (CIPRA)

CAPRISA is a designated UNAIDS Collaborating Centre for HIV Prevention Research.

The main goal of CAPRISA is to undertake globally relevant and locally responsive research
Most notable research

CAPRISA 003 SAPiT (Starting Antiretroviral Therapy at 3 Points in TB)

- Optimal timing for initiating ARV in HIV/TB co-infected patients,
- Adopted by the World Health Organisation (WHO), the US Department of Health and Human Services and South African Government in their treatment policies.

CAPRISA 004

- Tenofovir gel reduces HIV infections by 39 percent.
- Women who used the gel more often were up to 54 percent less likely to contract HIV.
- Reduces genital herpes infections by 51 percent
How we've always done it
Data Management Workflow

- CRFs completed
- QC on site
- Emailed to DataFax server
- Incorrect – ‘dirty’ QC
- QC checked by DM
- Validation by Data encoder 1
- Validation by Data encoder 2
- Corrections made at site
- QC report
- To site weekly
- Data checked and clean
How we decided

HELP!!!
CAP 087 STREAM

Dr Nigel Garett (CAPRISA)

Dr P Drain (UW)
Methods on choice of EDC system

• Proposed System X

• Compared 4 systems
The convincing

Presenting my findings
Traditional Paper based system

1. Evidence of IPT prescription
   - Yes
   - No
   - Not documented

2. Date started
   - [ ] [ ] [ ] [ ] [ ]
   - [ ] [ ] [ ] [ ] [ ]
   - [ ] [ ] [ ] [ ] [ ]

3. Date stopped
   - [ ] [ ] [ ] [ ] [ ]
   - [ ] [ ] [ ] [ ] [ ]
   - [ ] [ ] [ ] [ ] [ ]

Select yes, no, or not documented as appropriate.
What happens at the clinical site
Why EDC? General considerations

- Eliminate costs of printing CRFs, BIZHUB, patient files
- Eliminate cost & space for storage of these CRFs and the patient binders
- Risk of paper CRF loss / damage
- Real time data entry
- Fewer transcription errors – no handwriting
- E-signatures vs handwritten – possibly bad handwriting
Why EDC? General considerations

- Double data entry not required
- Anytime remote access to data
- Access to safety data
- Traceability of data with Audit trails
- Import laboratory results
- Adhoc reporting
Why EDC? Database considerations

- User defined roles
- Limited access to data after entry
- Edit checks pop up during real time data entry
- Electronic review of Reasons, Queries and Approvals
- Electronic QC resolutions
- Electronic monitoring
- Data security - Data stored on secure server
Workflow

Clinical Interviews

Data entry

Data validator oversight

Data cleaning

QC Officer

------Envelope Randomisation
Advantages of using Datafax

• Edit checks, auto calculations. Dialogue box pop up in real time

• Visit map for patient scheduling

• Electronic review of Reasons, Queries and Approvals

• Customizing roles for clinical site, data management and QA

• Import of laboratory results

• Remote access to the database
Response to suggestion

THEY SAID YES 😊
Methods using Datafax

- CRFS only appear after completing the one before (Dfneed)
- CRFS appear in order of completion, either required or optional
Methods using Datafax

- Creating different roles for different team members
- Access to monitoring team
- Email generated for each enrolment
- Importing of data from 2 different laboratories
- Immediate notification of abnormal results (import and calculated)
- No need to leave my desk and go out of the office 😊
Study statistics as at 31 August 2017

Total of 24 Datafax users
Data management = 4
Statisticians = 2
Clinical Site = 15
Quality Assurance = 3
Number Patients as at 31 August 2017 = 390
QC rate as at 31 August 2017 = 1
Challenges

- Staff Computer literacy – transition from writing on paper to edc
- Network downtimes – paper transcriptions and delayed data entry
- Customising multiple roles
- Exclusive access – needed to schedule downtimes
- No Audit trail for setup changes, have to rely on documentation
- Off line data entry on a tablet would be perfect
Lessons learnt

- Add Initials field for QA team
- Fax in Source data / Chart Notes with bar coded CRFs
Conclusion

• EDC yields higher data quality
• Efficient document storage system – minimal or no risk
• Adoption to EDC technology is relatively slow
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