Effective and Efficient QC Systems

Spilhaus CRS Zimbabwe

Omega Nyabadza
MTN Regional Meeting
28 October 2013
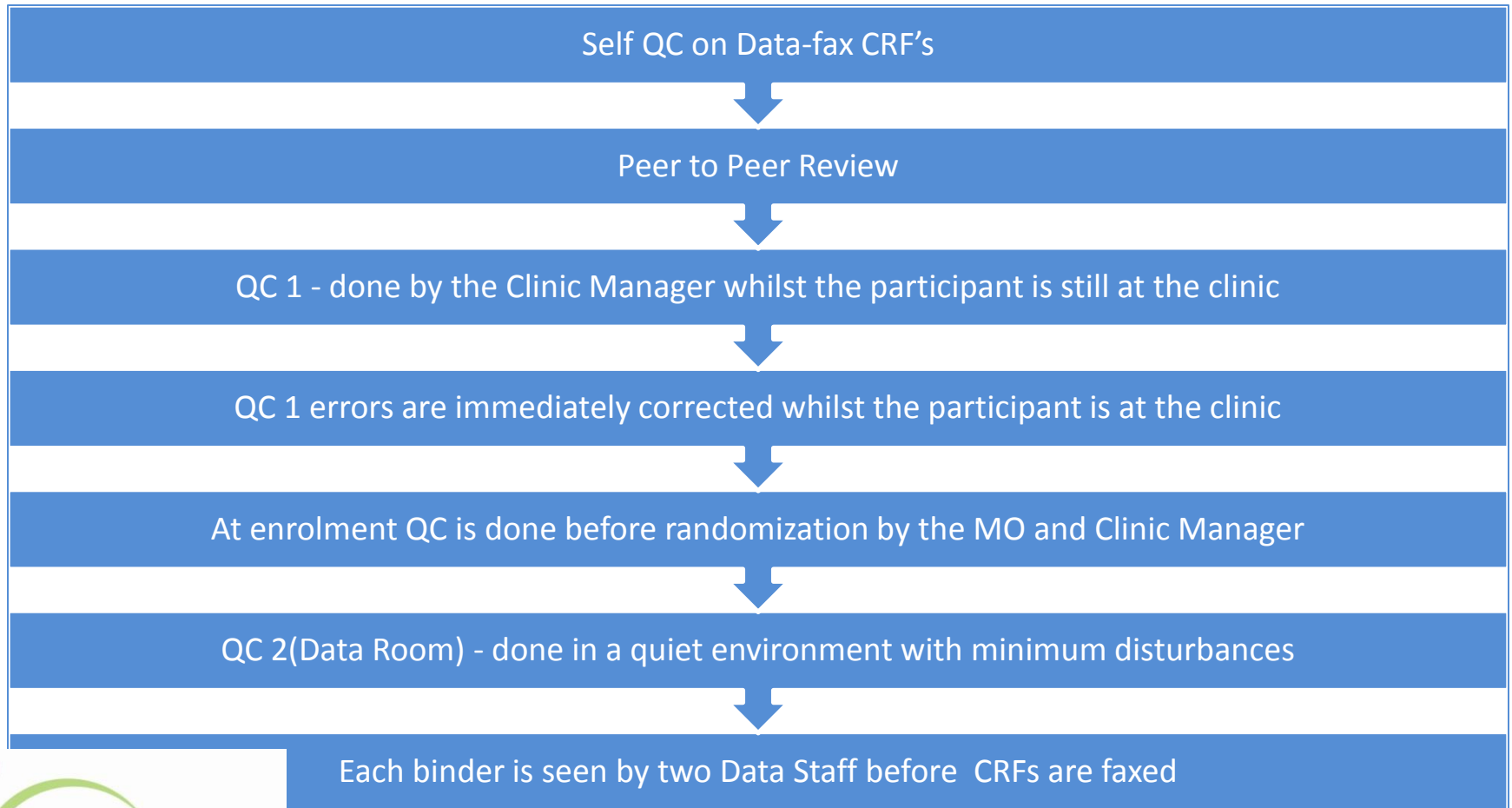
Spilhaus Site View

25 SEPT 2013

Spilhaus Clinic Staff

25 SEP 2013

Our QC Process...

Self QC on Data-fax CRF's

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Peer to Peer Review

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QC 1 - done by the Clinic Manager whilst the participant is still at the clinic

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QC 1 errors are immediately corrected whilst the participant is at the clinic

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At enrolment QC is done before randomization by the MO and Clinic Manager

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QC 2(Data Room) - done in a quiet environment with minimum disturbances

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Each binder is seen by two Data Staff before CRFs are faxed

...Our QC Process

Data Officers instantly take binders to Clinic Staff for resolution of errors on Datafax CRF's identified at QC2

Just before the form is faxed the CRF's are thoroughly reviewed .

Maximum use of the idatafax database, ensures that all queries are resolved on daily basis

Fridays have been assigned for QC's and trainings on the QC trends identified during the course of the week by Data Staff and Clinic Manager

Some Useful Tips

Site staff should have confidence in the data operations

- Minimal interference with Data operations

Dedicated Results nurse- to transcribe lab CRF's

QC Nurse

The Big Five Data Room Rules

Conducive Environment

Be familiar with study changes
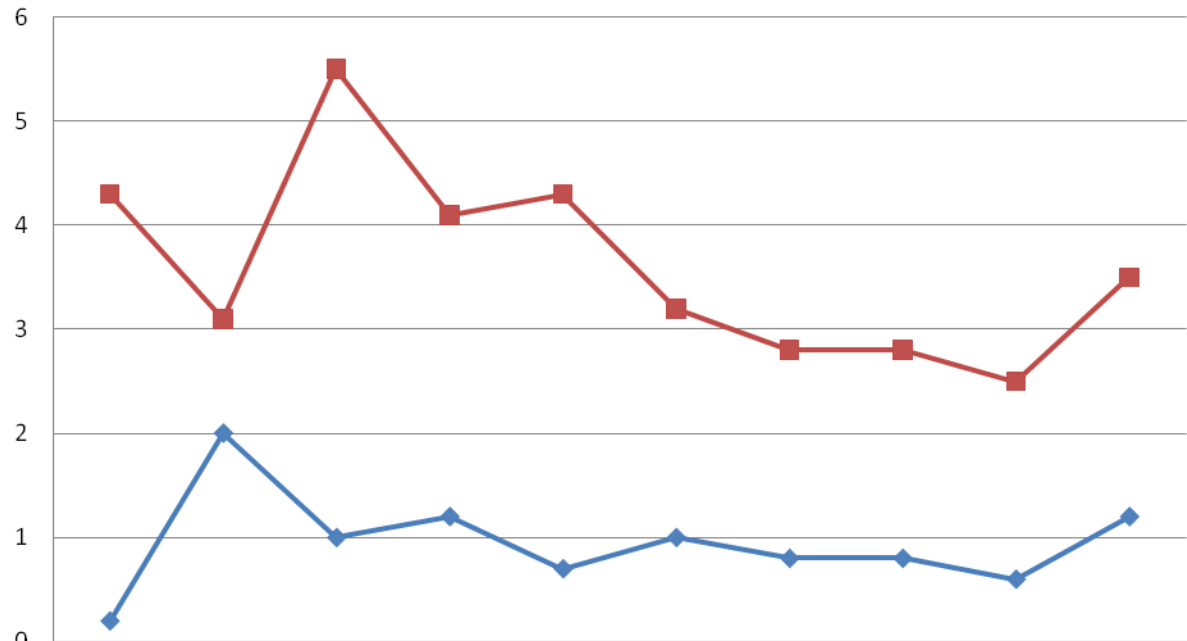
Study

Review & Implement

Identification of error trends discuss ,share and train

Spilhaus QC Rate Growth Chart

	Nov 12	Dec 12	Jan 13	Feb 13	Mar 13	Apr 13	May 13	Jun 13	Jul 13	Aug 13
SPILHAUS QC rate	0.2	2	1	1.2	0.7	1	0.8	0.8	0.6	1.2
Avg QC rate/Across All MTN sites	4.3	3.1	5.5	4.1	4.3	3.2	2.8	2.8	2.5	3.5

QC Rate (y-axis)

Months

Tools used during QC

- Pending issues log
- Notice boards
    - White boards,
    - Reminders and follow up written on them
- Visible Fliers

MTN- 020 QC Trends LOG

Date	QC Trend Noted	Staff Completing Form	Document(s) Affected	Is the Trend noticed by an individual or generally at the site?	How was the problem Addressed?	Date Issue addressed
05 Aug	Documentation of menses	CC	BFP-1 FP-1	Site	On-site Training	09 Aug 13
07 Aug	Driver's initials missing on lab request	Drivers	Lab request form	Individual	Training-Drivers	23 Aug 13
12 Aug	Generic Vs Trade Names	ALL Nurses	CM-1	Site	Email to SCHARP	Release of Data CM # 9
03 Sep	Administration of CRF	TM-1	PSE-1	Site	Site Training	06 Sep 13

QC Motivational Tips

- Right Attitude

(social issues usually overlap to work)

- Right Environment

(quiet environment improves concentration)

- Right Time

(perform all tasks on time)

LESSONS LEARNT

- Must be ready to concentrate!

- Develop the correct mindset

- Recognize when feeling distracted/drifting

- Dedicate time so you conduct the review process well

- Ask for a "fresh view/second eyes" (PEER-PEER REVIEW)

- Don't make assumptions – always double check

FORMULA FOR SUCCESS!!

Knowledge + Skills + Attitude

=

SUCCESS

Thanks to our Colleagues

- FHI
- SCHARP
- PPD
- All MTN-020 Sites
- UZ-UCSF

Questions?