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

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self QC on Data-fax CRF’s</td>
<td></td>
</tr>
<tr>
<td>Peer to Peer Review</td>
<td></td>
</tr>
<tr>
<td>QC 1 - done by the Clinic Manager whilst the participant is still at the clinic</td>
<td></td>
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<tr>
<td>QC 1 errors are immediately corrected whilst the participant is at the clinic</td>
<td></td>
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<tr>
<td>At enrolment QC is done before randomization by the MO and Clinic Manager</td>
<td></td>
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<tr>
<td>QC 2(Data Room) - done in a quiet environment with minimum disturbances</td>
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</table>
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.

Maximum use of the iDatafax database, ensures that all queries are resolved on a daily basis.

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

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

Identification of error trends discuss, share and train

Review & Implement
Tools used during QC

• Pending issues log
• Notice boards
  ▪ White boards,
  ▪ Reminders and follow up written on them
• Visible Fliers
<table>
<thead>
<tr>
<th>Date</th>
<th>QC Trend Noted</th>
<th>Staff Completing Form</th>
<th>Document(s) Affected</th>
<th>Is the Trend noticed by an individual or generally at the site?</th>
<th>How was the problem Addressed?</th>
<th>Date Issue addressed</th>
</tr>
</thead>
<tbody>
<tr>
<td>05 Aug</td>
<td>Documentation of menses</td>
<td>CC</td>
<td>BFP-1</td>
<td>Site</td>
<td>On-site Training</td>
<td>09 Aug 13</td>
</tr>
<tr>
<td>07 Aug</td>
<td>Driver’s initials missing on lab request</td>
<td>Drivers</td>
<td>Lab request form</td>
<td>Individual</td>
<td>Training-Driver</td>
<td>23 Aug 13</td>
</tr>
<tr>
<td>12 Aug</td>
<td>Generic Vs Trade Names</td>
<td>ALL Nurses</td>
<td>CM-1</td>
<td>Site</td>
<td>Email to SCHARP</td>
<td>Release of Data CM # 9</td>
</tr>
<tr>
<td>03 Sep</td>
<td>Administration of CRF</td>
<td>TM-1</td>
<td>PSE-1</td>
<td>Site</td>
<td>Site Training</td>
<td>06 Sep 13</td>
</tr>
</tbody>
</table>
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
And NOW!!!!!!

IT TAKES A TEAM
Thanks to our Colleagues

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