

Brook Jackson

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Wednesday, September 16, 2020 8:15 PM
To: William Jones
Cc: Marnie Fisher; Brook Jackson
Subject: RE: Keller QC status-

Hi William

Do you have any updates on the email below from talking with Katie Benitez?

Also, can you give an update on where Keller is on QC status?

Marnie/Brook- Since you will be in Keller tomorrow, I do want you both to focus on QCing charts while there. I know when on-site, it's very easy to get pulled into other things. But, right now **NOTHING** is more important than making sure we get all charts QC'd. I need the two of you to put a focus on QCing and I need an update tomorrow at the end of the day on how many charts the two of you QC'd as well as an update on what Ann has got done this week.

Please also make sure Anne stays focused on QCing tomorrow.

Regards,

Mercedes

Mercedes Livingston, CCRC

Chief Operating Officer

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From: William Jones <wjones@ventaviaresearch.com>
Sent: Monday, September 14, 2020 9:36 PM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: Re: Keller QC status-

Hello Mercedes,

The plan is for Anne to point them out at the time she encounters them for immediate reconciliation by Katie and the staff members. She is to notify me of any instance meeting these definitions via text message. We discussed this strategy in detail this morning.

Anne also made me aware that there are more charts that were placed within the cabinet that had not been QC'd. It appears to be an additional number of charts that I have not confirmed as to where they are coming from and why they were not accounted for in our process. They were not added to the QC bin as per the plan. I am uncomfortable with not knowing where they have been housed and will reach out to Katie Benitez tomorrow to discuss and revisit the plan. I want to make sure it has been fully implemented and understand the barriers prior to making changes but I also recognize if it will not work for them then we need to adjust where and how the folders are housed prior to QC. Marnie and I discussed the process similarities of Ft. Worth's QC process with differing bins for housing EDC, and QC and how that might work for Keller. My guess is that housing the EDC process in the clinic areas may be why we aren't getting them for QC (if they are behind with EDC) everything bottlenecks there and we have process failure. I will have to check with Katie to confirm this until then this is speculative.

I will place this on my calendar for tomorrow morning to discuss with Katie and follow up via email after we discuss.

Marnie, as a heads up I am also working on placing the observations in the spreadsheet as you've requested. Brook made me aware that she is experiencing technical difficulties and could not send to me so I've got it for Keller for last week.

Go team!

William

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From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Monday, September 14, 2020 8:41:03 PM
To: William Jones <wjones@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: Keller QC status-

Thank you, William for a detailed report.

What is the plan for follow-up with Katie to make sure the bolded items requiring prompt actions have been handled?

Regards,

Mercedes

Mercedes Livingston, CCRC

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From: William Jones <wjones@ventaviaresearch.com>

Sent: Monday, September 14, 2020 11:55 AM

To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>

Cc: Marnie Fisher <mfisher@ventaviaresearch.com>

Subject: RE: Keller QC status-

Good morning Mercedes!

Synopsis:

- Charts QC'd last week= 77
- QC should be up to date (100% QC'd) by Friday, September 18th. If this should change I will know before then via daily check-ins with Anne.
- Findings warranting immediate clarification=1, questionable participant enrollment clarified via documentation, progress note and sponsor notification/approval included in chart.
- General findings=
 - Staff moving too quickly/sloppy documentation, not documenting appropriately
- Regulatory implications=
 - Change/amend source documents secondary to compliance concerns (i.e., Impala Drug confirmation, source version control= patient info sheet, e-Diary log information)
- Site Manager met with staff and clarified/trained them on expectations/appropriate responses documented on source
- QC system implemented will reevaluate Thursday afternoon status, receive observations report on Friday.

Here is the detailed update from last week: 77 charts QC'd at Keller

9/8- Anne and William QC'd 21 Charts

9/9- William QC'd 30 Charts.

9/10- William QC'd 10 Charts. We reorganized the QC process as stated previously. Keller QC current up to September visits. Katie met with staff to make them aware and staff began implementing changes. Noticed in QC'd charts for Visit 2's Day 2s occurring later that day. Bucket used to hold charts needing QC was placed in Katie's office. Charts indicating Visit numbers were identified by dot (one dot means visit one, etc.)

9/11- William QC'd 6. Discussed with Katie QC findings for staff. Change: Note to file for writing on consent form not needed as threshold of 3 observations not met for writing in the remuneration on ICFs. Made Katie Benitez aware of ongoing findings:

- GP letter confirmation of fax not included within charts
- e-Diary loaded on personal device instead of times being noted in chart
- Revision of source document page 11 of 13 (visit 1, Day 1) and subsequent Creation of Note to File for all sites regarding e-diary question reminders. The e-dairy when loaded on personal devices defaults to 24 hour prompting. Source currently states Coordinator advised subject to schedule their alarm between 6-10pm, at 15 minute increments and notification will trigger every 30 minutes until the participant....Yes or No choices only. Will need to amend by adding N/A
- Dr. Fuller clarification sought for liver disease enrollment. Sponsor notified. Progress note added to chart.

I spent the remaining portion of Friday knocking out CITI trainings as I was notified my previous trainings did not count.

9/12- William QC'd 10 charts (worked approximately 4 hours). Printer cleaning warranted based upon observations from QC review of charts. William cleaned the printer to correct the blurry ICFs. Office closing early on Saturday, left at 1:45.

When I left Keller on Saturday, September 12th staff QC needs were down to the QC bucket (approximately 70 charts). There were no other charts in the cabinet for QC. This is important to note as I believe staff are now bringing charts over to the QC bucket as of last Thursday's implemented plan following EDC. I suspect that drift may still be at play until I confirm this afternoon with staff bringing charts to the QC bucket for review. This is based in part by staff continuing to search for folders throughout the clinic and calls into question a consistent process for patient binder flow...

The plan for the week was as follows: Katie and I discussed having Anne knock out the QC for the site and anticipate her completing by Wednesday of this week which should catch them up.

The plan is to notify staff daily, at the end of the day, of their QC charts and staff will address the following morning/reconcile within 24 hours of notification from QC staff.

I have touched base with Anne this morning to ensure she is aware of the change in practice (QC'ing and flagging and then compiling the information into spreadsheet for Friday).

I provided her with the following prompting for immediate notifications to Katie:

let Katie know of the **following immediately** as in my mind qualify as important and urgent clarification needed:

- **Eligibility/enrollment verification- informed consent signatures missing, discrepancies of dates on the ICF, no time documented on page 1, visit 1, Day 1 for consent signature.**
- **Missing information on clinic required observations that could impact participant safety (if some required observations were missed and no documentation as to why is present in the chart- for example, review of patient systems is missing, or the section of Medical History is blank and PI not signed-off indicating no MedHX)**
- **If MedHx/Con Meds reveals a condition prohibited by version 5.0 of the protocol that was missed (not addressed in Progress note or on CRF) by teammates and PI.**
- **If PI/Sub-I signatures are missing when they are expected (signature within 24 hour period).**
- **If there is no documentation of IP being given (blanks for IP administration documentation).**
- **If there is no documentation explaining a deviation of the requisite 30 minutes s/p IP administration (i.e. time less than 30 minutes, or more than 35)**

I think we have a good system in place so far and plan to assess on this afternoon with Anne and Katie.

I have included the two NTFs I crafted. Please let me know if you have concerns with these NTFs. I will send for Regulatory if no concerns/comments. I'd also like to include within the newsletter for the week to address notifying staff and training.

William

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Monday, September 14, 2020 9:05 AM
To: William Jones <wjones@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: Keller QC status-

William

Can you give us an update on where Keller was on QCing by the end of the week? I know the team worked on Saturday.

Also, were the action items (NTF) below completed as well, sent for signature through Complion?

Regards,

Mercedes

Mercedes Livingston, CCRC

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From: William Jones <wjones@ventaviaresearch.com>
Sent: Tuesday, September 8, 2020 8:25 PM
To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: Keller QC status-

Hello Mercedes,
I wanted to be sure to close the loop with you as promised.

Anne and I reviewed 21 charts today. When I arrived this morning I had a difficult time locating charts to QC because I misunderstood how the charts were kept in the cabinet Friday on the first two shelves, and this morning I saw what appeared to be the majority of the charts as having undergone QC.

To be certain before I left, I asked Katie if she could help me identify the charts and best understand their system and processes so one would know when a chart is ready to be QC'd. Katie showed me where the charts to be QC'd are all located (they file them by patient number in the cabinet) as well as a clear bucket (similar to Ft. Worth) that I had not seen. That said, it looks as if there are approximately less than 200 charts that need to be QC'd as an estimate. Team, I apologize for this oversight on my part. These charts are like Gremlins fed after midnight!

This will take me and Anne the remainder of the week to get through. I will devote tomorrow and Thursday towards knocking that out to catch them up. In my observation, Anne is noting the findings in an Excel spreadsheet versus my noting on the one page document (which is much quicker). This should be noted as an observation as to why it takes her a bit longer to complete as it takes her an additional 5-7 minutes to enter the information on each chart into the Excel spreadsheet, and another 5 minutes to note it on stickies. I will discuss this with her on tomorrow. For now, and to help her become more efficient, I believe it important for her to adopt the same practice as I (write on the one sheet and stickies) and then she can go back and enter the findings on the spreadsheet at the end after we have caught up. In my mind, and to organize workflow, I'd like to make that the goal for QC's on Friday, that way we can have a report of observations for the week and I can categorize it, looking for trends for training purposes. That is a goal I have and I see us moving there fairly soon.

Also, as promised and to follow-up regarding the observations/Notes to File mentioned during this morning's call:

- A NTF is warranted for all sites to address the C4591001 Visit 2 source for including the drug confirmation.
- A NTF is warranted for Keller for not using the correct version for C4591001 Visit 2 source dated September 3, 2020.
- A NTF is warranted for instances of coordinators writing on the ICF to correct patient stipend amounts and amend visit 4 information
 - Regulatory follow-up:
 - Modification of ICF should be submitted to the IRB, subjects reconsented given visit 4 has changed from remote/phone call to in-person visit
 - Will this change the amount of time estimated for obtaining consent/modifications to the study/contract
- An outline of the set-up for the patient study binder is warranted. I discussed this with Katie and will work towards developing a study training for their site.

Thank you Mercedes for the request. To close the loop, I am including Marnie on this email as well so she is aware. If it's okay with you both, I'd like to continue looping you in on what I'm seeing and get your feedback/thoughts/clarifications.

Marnie, with these observations I noticed this evening this will change the plan for me being in Ft. Worth on Thursday to meet you in person. Would you be okay with me carving out some time to meet via Microsoft Teams with you all or push meeting to Friday instead? I will support what you suggest.

Go team!!!

William