

- Question: The weekly email/newsletter is a great idea. Thank you for sharing that. But how do you communicate on-going issues that require real time attention?

Answer: If they require real time attention, then we would have one-on-ones/reach out to specifically address those issues immediately with those individuals. Also, there are sometimes time sensitive communications that we will send out, if we have.

- Question: What methods/systems do you use for identifying trends in noncompliance? How do you determine a threshold for when noncompliance should be considered a trend?

Answer 1: We just use an Excel document in our SharePoint because we don't have a management system yet. So, we just use the basics and create each of the spreadsheets with what we want to put in there.

Answer 2: We look at all the findings over time to see the count of how many times events may occur. If it is a finding that we see recurring quite frequently, then we would think something of that nature would require either reeducation, or maybe we are looking at a systemic issue. We make a lot of quarterly comparisons based on the information we do track a do an analysis of that data.

- Question: Mary -can you provide your orientation tracker/all lists mentioned?

Answer: Those available will be sent to Rose for distribution.

- Question: Can you share the data dictionary for the REDCap tracker?

Answer: This will be sent to Rose for distribution.

- Question: Talking about non-compliance, do you have a min threshold that if passes is classified noncompliance. For example, if a patient has missed their dose 2 times in 28-day cycle, and then 3 times next cycle. Will you classify this non-compliance?

Answer (Stephanie): Personally, to me this is continued non-compliance and so if an issue continues even after intervention and it continues at an increased rate, this will continue to be considered non-compliance. I think we all probably have our own definitions or thresholds and how we categorize them.

Answer (Rose): In an article previously reviewed, it was determined that if a patient had taken <80% of their drugs, the study data would be impacted.

Note from Rose– If your site finds something in the protocol that is unrealistic and it's difficult to for your site or patient to do, like compliance or taking pills, you can always give that information to either your auditors when on site, or to the study coordinators. They do take this information back to those writing the studies and statisticians, who take this into consideration and may modify the trial to make it more realistic for the patient.

Polling Questions

1. *What type of QA activities are done at your site?*

1. Thorough review at the time of an audit.
2. Ongoing source checks of data entered in RAVE
3. Proactive reviews of research activities
4. Use of ongoing metrics
5. Ongoing education and training

Answer choices and percent of respondents selecting the choice:

- a. 1 - **5% of respondents selected this response**
- b. 1, 2 & 3 - **5% of respondents selected this response**
- c. 2 & 3 - **5% of respondents selected this response**
- d. 3 & 4 - **No respondents selected this response**
- e. 1-5 - **80% of respondents selected this response**
- f. Other - **5% of respondents selected this response**

2. *Do you have a Quality Assurance program or QA Specialist at your site?*

Answer choices and percent of respondents selecting the choice:

- a. No - **15% of respondents selected this response**
- b. We have added this within the last year.
- **6% of respondents selected this response**
- c. Yes, have had this greater than a year.
- **71% of respondents selected this response**
- d. Is this required? - **9% of respondents selected this response**