UNIVERSITY OF Cincinnati

REGULATORY TIPS AND UPDATES– DID YOU KNOW?

IM Regulatory Newsletter

In this issue:

IRB accrual questions for Continuing Reviews – What is what? What are they looking for?

Clarification on the WCG questions for a continuing review:

1. How many subjects have been enrolled in the research? Consent was obtained (if applicable) or if no consent was required, they were included in the research. This should be the total of your screen fails, withdraws (on their own AND by study team), those lost to follow-up, those who completed the study, and those still active on study.
2. How many subjects failed screening? They signed consent, enrolled, but didn't qualify
3. How many subjects decided on their own to stop taking part in the research? Withdrew on their own. Does not include screen fails.
4. How many subjects did you remove from the research before reaching a study endpoint? Withdrawn by the study team for any reason – does not include screen fails and does not include lost to follow-up.
5. How many subjects are lost to follow up?
6. How many subjects completed the research? All study interventions and procedures are finished. They are not active or in follow-up. They completed the study. This does not include withdraws, screen fails, or lost to follow-up.
7. How many subjects remain on study? WCG combines active and those in follow up into one category. This answer would be how many people are still active in any way – including still receiving intervention and/or still completing any protocol procedures.

Clarification on the Advarra questions for a continuing review:

1. Enrollment Status: open/closed/closed but there are still active subjects.
2. Total number of subjects who did not meet initial inclusion/exclusion criteria (screen failures): They signed consent, enrolled, but didn't qualify
3. Total number of subjects who prematurely terminated from participation after meeting enrollment criteria: Consented, qualified, didn't finish study by their own choice, or were removed (withdrawn)
4. Please provide the reasons for each premature termination: need to provide a reason for each
5. Did any of the premature terminations involve a death ***related to the study drug, device, or intervention***
6. Total number of subjects who have completed their participation: All study interventions and procedures are finished. They are not still active or in follow-up. They completed the study. This does not include withdraws, screen fails, or lost to follow-up.
7. Total number of subjects still active in the research study: Active here means participant is ***still receiving study related intervention***
8. Total number of subjects in follow-up **only:** Follow-up here means completed all interventions (if applicable), but are still being followed, and may still have procedures – they are still active participants – just not receiving active intervention.
9. Total number of subjects who signed the informed consent form(s): This should equal total of your screen fails, withdraws, completed, active and follow-up patients.
10. Date of first subject consented:

Accrual Questions can be confusing as to what the asking IRB is really looking for. Often their question doesn't align with our enrollment terminology at our site. In an effort to eliminate confusion, and make sure we are reporting accurate numbers, please use the above definitions as a guide to submit your answers for continuing reviews to ARS IM Regulatory.

If you have any questions, please do not hesitate to reach out to: IMRegulatory@uc.edu

For more information, please click: Tools and Templates

Thank you!