


COMMON MISTAKES MADE IN CLINICAL TRIALS

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Case Study 1

Dose Modification & Documentation

- 54 y/o female had a grade 3 toxicity on a treatment trial for SOC medication. There was no clear direction on what to do if patient came off all chemotherapy while on the trial.
- The CRA contacted the study chair to inquire about patient coming off the trial as patient would only be left on single agent bevacizumab (study agent) once the other agent was discontinued. The CRA received a response from the study chair stating that the patient should stay on bevacizumab as a single agent and continue on the study.




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Case Study 1

Dose Modification & Documentation

- A few years later during an audit, this case was reviewed.
- There was not any documentation that the study chair was contacted or what recommendations were made.
- There was no documentation as to why bevacizumab was given as a single agent
- This incident resulted in a major deviation.



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Slide 3

- A1** I don't know if I state that the the study chair stated that he did not give this directive as a SC would not remember having been asked this question. You should instead that the CRA had no documentation that the SC was contacted or what recommendations were made. There was no documentation made by the phys as to why Bev was give as a single agent.

Author, 9/10/2019

Case Study 2-Pill Compliance

- 41 y/o female on S1207 receiving endocrine therapy + everolimus/placebo. Patient was having a difficult time with pill compliance, as evidenced by incomplete diary and incorrect pill count.
- The research nurse was concerned that the patient missed multiple days of treatment and may soon meet criteria to come off the protocol because of too many missed doses.



Case Study 2-Pill Compliance

- Upon further discussion with patient it was found that pill diary was not working for her and that it was actually a barrier for her to remember to take her pill. She had requested if she could use the alarm on her phone as a reminder for her to take her pills.
- The research nurse and patient were able to work out a way where the patient would document on the pill diary when it was convenient for her but would use the alarm on her phone to remind her to take the pill.



Slide 4

A2 I think you should provide the following: how were you aware that she was not compliant i.e multiple missed doses on the diary or pill count; 2) did the protocol require her to come off protocol because she had missed too many doses. Reminder, patients must meet the protocol criterias for coming OFF Study. If using the phone to assist with compicance, how would you document compliance.

Author, 9/10/2019