Common Mistakes by Programmers & Remedies

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1. Column labels should be displayed correctly like INCLUSION should be “Inclusion”, DT should be “DT” and YES/NO values should be “YES/NO”.

2. No footnotes for given subscript [1] and Closing Parenthesis is going open.

3. These two columns were removed in updated /Current SAP.

4. The order of visit variable is not correct.

5. Date of Expiration (15/05/2012) was after than time (02/05/2012) which is not right.

6. Transcription of Treatment variable with treatment info.

7. Based on the title, only >= 5% Pts should display in the table.

8. Count and Percentages are not matching for Sex

9. Patients with at least 1.4C is more than No. of patients in treatment

10. Grouping not done for 2 variables

11. Derivatives of IT or PP Hags wrong

12. Median & Max variables were inter changed and may be missing age was included under <18 or >35 group as we have 12 patients but <=18 only.

13. Age value less than 10 yrs so it may be due to error in or wrong calculation of Age variable

14. Last dose date is more than study termination date

Simple Remedies

1. Before submitting for validation need to double check all the labels are displayed correctly or not
2. Always use the final version of study documents
3. Check for Subscriptions and corresponding information, extra spaces before submitting for validation
4. Need to confirm the display of decimal places for derived variables with stat if not mentioned in SAP or study docs.
5. Review the report to check any column values are truncating
6. Give a glance to see the percentages are matching correctly
7. Check for “Are we using correct macro variables to create percentages”
8. Use defensive coding to avoid loosing the data.
9. Check the study documents and raise issue with DM.

Simple Mantra

“Self Validation” and “Continuous Learning” are the best methods to avoid 50 to 60% of mistakes

Try to work towards “First Time Right Approach (FTRA)”