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Question 1

Question Type: MultipleChoice

Given the following SAS program:

```
data one;
  input subjid 1-2 trt $ 4-5 result $ 6-7 dtime 9-10 age 11-12;
  datalines;
01  CR 0 56
02  A  PD 1 52
03  B  PR 1 47
04  B  CR 2 29
05  1  SD 1 39
06  C  SD 3 21
07  C  PD 2 90
01  A  CR 0 43
03  B  PD 1 56
;
run;
```

Which statement correctly identifies invalid values in the variable TRT, if only the values 'A', 'B', 'C' are valid?

Options:

- A- if indexc(TRT, 'ABC') eq 0 then output;
- B- if index(TRT, 'ABC') eq 0 then output;
- C- if find(TRT, 'ABC') eq 0 then output;

D- if `indexw(TRT, 'ABC') eq 0` then output;

Answer:

A

Question 2

Question Type: MultipleChoice

A Statistical Analysis Plan describes a clinical trial as "A 12 week, double-blind, placebo-controlled, randomized, multi-center study."
Double-blind refers to which groups in this study?

Options:

- A-** treatment and control group
- B-** investigator and subjects
- C-** statistician and sponsor
- D-** sponsor and investigator

Answer:

B

Question 3

Question Type: MultipleChoice

A patient received at least one dose of study medication prior to withdrawing from a study. Which analysis population would always include this patient?

Options:

A- efficacy

B- intent to treat

C- per protocol

D- safety

Answer:

D

Question 4

Question Type: MultipleChoice

What is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects?

Options:

A- 21 CFR Part 11

B- Good Clinical Practices

C- MedDRA

D- WHODrug

Answer:

B

Question 5

Question Type: MultipleChoice

What is the main focus of 21 CFR Part 11?

Options:

- A- electronic submission requirements
- B- trial safety requirements
- C- statistical calculation requirements
- D- trial protocol requirements

Answer:

A

Question 6

Question Type: MultipleChoice

An action plan that describes what will be done in a drug study, how it will be conducted, and why each part of the study is necessary is called:

Options:

A- a clinical trial plan

B- a protocol

C- a data management plan

D- a statistical analysis plan

Answer:

B

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