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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:

Α

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:	
В	
Question 3	
Question Type: MultipleChoice	
A patient received at least one dose of sinclude this patient?	study medication prior to withdrawing from a study. Which analysis population would always
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:

В

Question 5

Question Type: MultipleChoice

Options:

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

Answer:

Α

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:

В

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