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Clinical Trials Programming Using SAS 9

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QUESTION: 92

A Statistical Analysis Plan (SAP) defines the selection process for baseline records. This instructs the programmer to choose the last non-missing analyte value prior to first study drug administration (date/time). The DEMO data set contains the date/time of first study drug administration for subject:

```
STYSID1A      RFSTDTM
0001_0001      19970109:08:32
```

The LABRS data set contains the lab data assessments:

```
STYSID1A      LBDTTM      HBA1C      GLUC      SGOT      SGPT
0001_0001      19961216:09:26      5.1      125      32.2      29.1
0001_0001      19961223:08:18      6.1      136      34.1      30.1
0001_0001      19961230:09:12      8.1      225      31.8      29.5
0001_0001      19970106:09:01      6.7      158      .      29.7
0001_0001      19970110:08:43      6.6      150      30.5      30.2
```

What will be the resulting baseline values, as selected per the SAP instructions?

- A. HBA1C GLUC SGOT SGPT
 5.1 125 32.2 29.1

- B. HBA1C GLUC SGOT SGPT
 8.1 225 31.8 29.5

- C. HBA1C GLUC SGOT SGPT
 6.6 150 30.5 30.2

- D. HBA1C GLUC SGOT SGPT
 6.7 158 31.8 29.7

- A. Option A
- B. Option B
- C. Option C
- D. Option D

Answer: D

QUESTION: 93

From the Statistical Analysis Plan, patients age is calculated as an integer relative to date randomized divided by 365.25. Given the following annotated CRF:

Date of birth	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	BIRTHDT
	Day	Month	Year					
Sex	[M] <input type="checkbox"/>	Male						SEX (SEX)
	[F] <input type="checkbox"/>	Female						

RANDOMISATION NUMBER RAND								
Record randomisation number								
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	RANDNUM
Date of randomisation								
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	RANDDT
	Day	Month	Year					

Which programming code defines the patient's age?

- A. `age = int((birthdt-randdt)/365.25);`
- B. `age = int((randdt-birthdt)/365.25);`
- C. `age= int(yrdif(birthdt,randdt, "act/365.25"));`
- D. `age = int((today()-birthdt)/365.25);`

Answer: B

QUESTION: 94

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:

- A. a clinical trial plan
- B. a protocol
- C. a data management plan
- D. a statistical analysis plan

Answer: B

QUESTION: 95

What is the main focus of 21 CFR Part 11?

- A. electronic submission requirements
- B. trial safety requirements

- C. statistical calculation requirements
- D. trial protocol requirements

Answer: A

QUESTION: 96

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

- A. 21 CFR Part 11
- B. Good Clinical Practices
- C. MedDRA
- D. WHODrug

Answer: B

QUESTION: 97

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

- A. efficacy
- B. intent to treat
- C. per protocol
- D. safety

Answer: D

QUESTION: 98

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?

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

Answer: B

QUESTION: 99

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?

- 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

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