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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:

STYSIDLA	RFSTDTTM
0001_0001	19970109:08:32

The LABRS data set contains the lab data assessments:

STYSIDLA	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

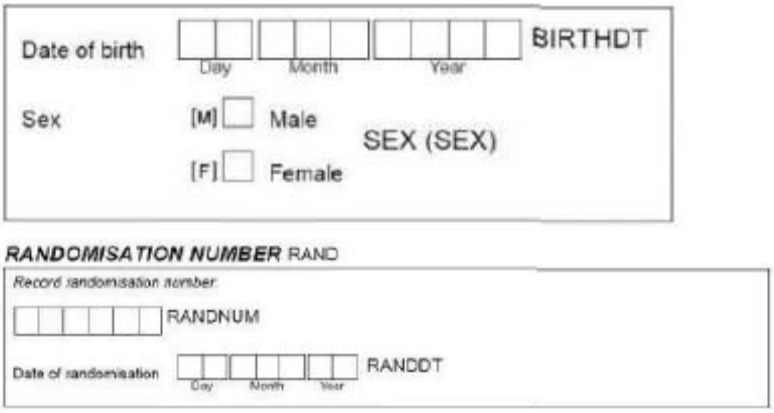
D.

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:



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 O 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 O 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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