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Question 1

Question Type: MultipleChoice

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"/>	RANDDT
	Day	Month	Year					

Which programming code defines the patient's age?

Options:

- 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 2

Question Type: MultipleChoice

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
```

Options:

A- Option A

B- Option B

C- Option C

D- Option D

Answer:

D

Question 3

Question Type: MultipleChoice

Which statement correctly describes an aspect of a Phase II clinical trial?

Options:

A- randomized controlled multicenter trials on large patient groups

B- designed to assess the pharmacovigilance, pharmacokinetics, and pharmacodynamics of a drug

C- in vitro and in vivo experiments using wide-ranging doses of the drug

D- designed to assess how well the drug works

Answer:

D

Question 4

Question Type: FillInTheBlank

Which CDISC filename contains the following items?

- * Variable attributes
- * Controlled terminology
- * Computational methods

Enter your answer in the space below (Case is ignored. Do not add leading or trailing spaces to your answer.).

Answer:

Question 5

Question Type: MultipleChoice

Where would you store a value collected on a case report form but not defined in an SDTM domain?

Options:

A- RELREC

B- DM

C- SUPPQUAL

D- SC

Answer:

C

Question 6

Question Type: MultipleChoice

The purpose of the ADaM model is to provide a framework that:

Options:

- A- enables the tabulation of the raw source data
- B- enables the creation of study patient profiles
- C- enables the statistical analysis of the data
- D- can be used to generate the CDISC ODM

Answer:

C

Question 7

Question Type: MultipleChoice

Define.xml is an XML-based submission of a clinical study's:

Options:

- A- results

B- metadata

C- data

D- protocol

Answer:

B

Question 8

Question Type: MultipleChoice

Identify the data structure with the following characteristics:

- * Contains one or more records per subject, per analysis parameter, and per analysis timepoint.
- * May be derived from findings, events, interventions and special-purpose SDTM domains, or other ADaM datasets.
- * A record can represent an observed, derived, or imputed value required for analysis.

Options:

- A- General Data Structure (GDS)
- B- Basic Data Structure (BDS)
- C- Subject Level Analysis Data Set (ADSL)
- D- Event Level Analysis Data Set (ADAE)

Answer:

B

Question 9

Question Type: MultipleChoice

This question will ask you to provide a missing option.

The following program is submitted to create a transport file for multiple data sets:

```
libname derived 'C:\Data\Derived';  
libname xptout xport 'C:\Data\transportfiles\transport.xpt';  
proc copy in=derived out=xptout <insert missing option>;  
run;
```

Which option will limit the files that are copied to type data?

Options:

- A- intype=data
- B- memtype=data
- C- entrytype=data
- D- include=data

Answer:

B

Question 10

Question Type: MultipleChoice

The following SAS program is submitted:

```
data BASE_BP (drop=vstestcd);  
  set VS (keep=usubjid vsstresn vstestcd);  
  if vstestcd in('DIABP','SYSBP');  
run;
```

Which alternative program creates an equivalent BASE_BP data set?

Options:

A- proc sort data=VS (keep=usubjid vsstresn vstestcd)
out=BASE_BP (drop=vstestcd);
where vstestcd in('DIABP','SYSBP');
by usubjid;
run;

B- data BASE_BP;
set VS (keep=usubjid vsstresn);
if vstestcd in('DIABP','SYSBP');
run;

C- proc sort data=VS (keep=usubjid vsstresn vstestcd)
out=BASE_BP (drop=vstestcd);
by usubjid;
if vstestcd in('DIABP','SYSBP');
run;

D- data BASE_BP (keep=usubjid vsstresn vstestcd);
set VS (drop=vstestcd);
if vstestcd in('DIABP','SYSBP');
run;

Answer:

A

Question 11

Question Type: MultipleChoice

Given the SAS data set WORK.BP

```
subjid SBP  DBP
----- ---  ---
01562  145  92
02457  130  87
03489  117  78
01598  135  85
02678  145  79
```

The following SAS program is submitted:

```
data
  WORK.HIGHBP
  WORK.NORMBP
  WORK.INVESTBP;
set WORK.BP;
if SBP gt 140 and DBP gt 90 then output WORK.HIGHBP;
if SBP lt 120 and DBP lt 80 then output WORK.NORMBP;
else output WORK.INVESTBP;
run;
```

What is the result?

Options:

- A-** WORK.HIGHBP has 1 observation
WORK.NORMBP has 1 observation

WORK.INVESTBP has 3 observations

B- WORK.HIGHBP has 1 observation

WORK.NORMBP has 1 observation

WORK.INVESTBP has 4 observations

C- WORK.HIGHBP has 1 observation

WORK.NORMBP has 1 observation

WORK.INVESTBP has 2 observations

D- WORK.HIGHBP has 2 observations

WORK.NORMBP has 2 observations

WORK.INVESTBP has 3 observations

Answer:

B

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