Free Questions for A00-281 by certsinside

Shared by Porter on 12-12-2023

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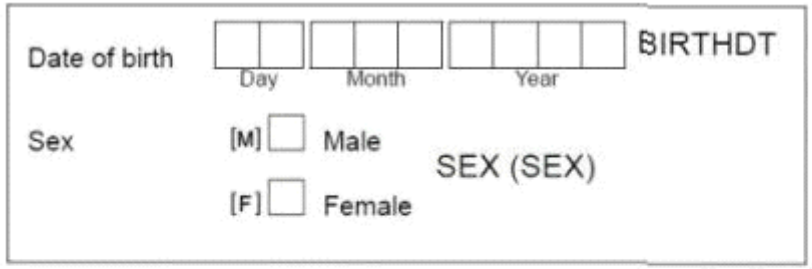
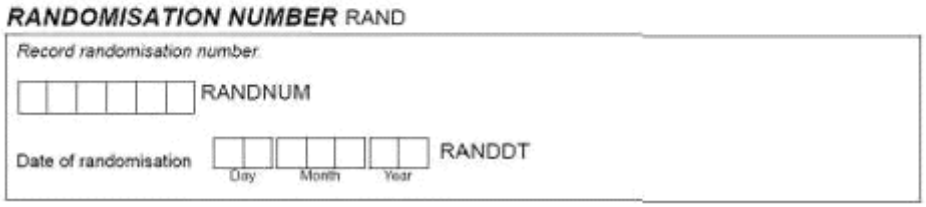
Question 1

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:





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	RFSTDTTM
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**

Given the following data set:

STYSID1A	COLLDTM	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

Which type of clinical trials data is this?

Options:

A- Laboratory

B- Baseline

C- Medical History

D- Vital Signs

Answer:

A

Question 8

Question Type: **MultipleChoice**

Which CDISC standard is concerned with the development of simplified case report forms?

Options:

A- Clinical Data Acquisition Standards Harmonization (CDASH)

B- Operational Data Model (ODM)

C- Study Data Tabulation Model (SDTM)

D- Trial Design Model (TDM)

Answer:

A

Question 9

Question Type: MultipleChoice

Identify the CDISC model with the following characteristics:

* XML-based content and format standard

* facilitates the archive and interchange of the metadata and data for clinical research

* provides an accurate audit trail that is 21 CRF Part II compliant

Options:

A- Analysis Data Model (ADaM)

B- Operational Data Model (ODM)

C- Study Data Tabulation Model (SDTM)

D- Trial Design Model (TDM)

Answer:

B