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QUESTION 1

A subject reports a medication started in March of 2007 but cannot recall the day number. What is the value stored in the SDTM domain CM.CMSTDTC variable?

A. 00MAR2007

B. 2007 03

C. MAR2007

D. 2007-03

Correct Answer: D

QUESTION 2

Given the following work data set containing Treatment-Emergent Adverse Events:

subject	aebodsys	aedecod	aesev
001	NERVOUS SYSTEM DISORDERS	DIZZINESS	1
001	NERVOUS SYSTEM DISORDERS	HEADACHE	2
001	NERVOUS SYSTEM DISORDERS	HEADACHE	3
001	NERVOUS SYSTEM DISORDERS	DIZZINESS	2
001	NERVOUS SYSTEM DISORDERS	LETHARGY	3
002	NERVOUS SYSTEM DISORDERS	DIZZINESS	1
002	NERVOUS SYSTEM DISORDERS	DIZZINESS	2
003	NERVOUS SYSTEM DISORDERS	HEADACHE	3
003	NERVOUS SYSTEM DISORDERS	HEADACHE	3
003	NERVOUS SYSTEM DISORDERS	LETHARGY	2
004	NERVOUS SYSTEM DISORDERS	LETHARGY	2

AESEV (Severity : 1 = Mild, 2 = Moderate, 3 = Severe

And a B: Severity table:

	Subject n (%)
NERVOUS SYSTEM DISORDERS	
Mild	n (p)
Moderate	n (p)
Severe	x (p)

In the space below, enter the numeric value of x for "Severe" events under HEADACHE.

Correct Answer: 2

QUESTION 3

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You want to calculate the p-value of Fisher\\'s exact test for a 3x3 table. Which option must you add to the TABLES statement of PROC FREQ?

A. CHISQ

B. CMH

C. EXACT

D. EXPECTED

Correct Answer: C

QUESTION 4

Which option for PROC COMPARE will list all observations and variables found in only one of the two data sets being compared?

A. LISTALL

B. OUTALL

C. ALLOBS

D. OUTDIFF

Correct Answer: A

QUESTION 5

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

A. Analysis Data Model (ADaM)

B. Operational Data Model (ODM)

C. Study Data Tabulation Model (SDTM)

D. Trial Design Model (TDM)

Correct Answer: B

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