Training Curriculum: MedDRA: Safety Data Analysis and SMQs Quiz
Question 1

Which of the following statements are true?

a) Primary SOC allocations are pre-defined and should only be changed through the MSSO’s Change Request process
b) Data reviewers should alter the primary SOC allocations as necessary to fit the product’s safety profile
c) Primary SOC allocations support consistent data reporting to regulators
d) Secondary SOCs can provide alternate views of data
Which of the following statements are true?

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b) Data reviewers should alter the primary SOC allocations as necessary to fit the product’s safety profile

c) Primary SOC allocations support consistent data reporting to regulators

d) Secondary SOCs can provide alternate views of data
Question 2

Which SOCs are non multi-axial and should always be considered when retrieving data?

a) SOC Congenital, familial and genetic disorders
b) SOC Infections and infestations
c) SOC Investigations
d) SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps)
e) SOC Social circumstances
f) SOC Surgical and medical procedures
Question 2 - Answer

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Question 3

In a data set displayed by primary SOC, under which SOC would you find PT *Congenital HIV infection*?

a) SOC *Congenital, familial and genetic disorders*
b) SOC *Immune system disorders*
c) SOC *Infections and infestations*
d) SOC *Pregnancy, puerperium and perinatal conditions*
In a data set displayed by primary SOC, under which SOC would you find PT *Congenital HIV infection*?

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Question 4

Which of the following statements about the MedDRA Data Retrieval and Presentation: Points to Consider document are true?

a) It is endorsed by the ICH
b) It is updated with each release of MedDRA
c) It is most effective when used in conjunction with the MedDRA Term Selection: Points to Consider document
d) It is recommended to be used as the basis of organizations’ own data retrieval guidelines
Question 4 - Answer

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Question 5

Which options can Standardised MedDRA Queries use to refine searches?

a) Narrow and broad searches
b) Algorithms
c) Hierarchical structures
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