Source Documents Activity Answer Key

Activity Title: To Enroll or not Enroll? The Case if Miss. Smith

Read the below source document verification case-based scenarios carefully. Upon completing the reading, proceed to discuss findings and issues with your group, write the answer to all the questions listed below, and prepare to share your answers.

1. Miss. Bandile Smith is enrolled for a HIV prevention study. The inclusion criteria say that the patient is eligible for the study if:
   Age of 18 to 35 years females
   Negative HIV-1 and -2 blood test within 30 days prior to enrollment conducted at a DAIDS approved site lab
   Agree to consistently use effective contraception from 30 days prior to enrollment through 4 months after the last use of study product
   Weight <120kg
   Heart rate > 65 BPM
   Respiratory rate < 20
   Average blood pressure ≥ 140/100

   Please review the progress notes below and answer the questions with appropriate reasoning if the subject can be enrolled for the study or not?

14-April-2019

Bandile Smith
DOB 11 Feb 1999 Chart#1122

Miss. Bandile Smith is a 20-year old girl with a negative HIV test result. She has been enrolled for the HIV prevention study at site 101. She has signed the informed consent form and has been all the relevant information regarding the protocol.

HEIGHT	169 CM	Jesse Smith at 14 April 2019 - 08: 02
WEIGHT	108 KG	Jesse Smith at 14 April 2019 - 08: 02
TEMPERATURE	37°C	Jesse Smith at 14 April 2019 - 08: 04
HEART RATE/ PULSE	77 BPM	Jesse Smith at 14 April 2019 - 08: 0 6
RESPIRATORY RATE	18	Jesse Smith at 14 April 2019 - 08: 0 7
SYSTOLIC/DIASTOLIC	130/90 MMG	Jesse Smith at 14 April 2019 - 08: 08

Source Documents Activity Answer Key

1. Identify the key issues in the above case study.

   Blood pressure is lower than required as per the protocol. There is no mention to consistently use effective contraception from 30 days prior to enrollment through 4 months after the last use of study product

2. Based on the above data, can the participant be enrolled in the study? Provide your reasoning for your response.

   As participant doesn't meet the inclusion criteria, participant cannot be enrolled in the study

2. Below is Miss. Bandile's Smith lab report. Please review the progress notes below and answer the questions with appropriate reasoning if the subject can be enrolled for the study or not?

LOCAL LABORATORY REPORT
ACCESSION NO. G59335
Page 1 of 3

Site no 101

14-April-2019
Bandile Smith

CHEMISTRY			CLINICAL SIGNIFICANCE NO	YES*
Total Bili	0.8	0.2-1.2 mg/dL		
Alk Phos	106	31-110 U/L		
ALT (SGPT)	40	6-43 U/L		
AST (SGOT)	33	11-36 U/L		
Urea Nitrogen	10	4-24 mg/dL		
Creatinine	0.8	0.8-1.6 mg/dL		
Uric Acid	7.0	4.6-8.05 mg/dL		
Calcium	9.2	8.4-10.3 mg/dL		
Phosphorus	3.9	2.2-5.1 mg/dL		
Total Prot	8.1	6.1-8.4 g/dL		
Albumin	4.6	3.3-4.9 g/dL		
Sodium	138	132-147 mEq/L		
Potassium	4.7	3.4-5.4 mEq/L		
Chloride	110	94-112 mEq/L		
HIV test	Negative			

Investigator Signature:___ Date_____

Source Documents Activity Answer Key

1. Identify the key issues in the below lab report?

   No signature and date by the PI. PI has not even mentioned if the values are clinically significant or not. "HIV test report from local clinic indicate a negative HIV Test result". Site would not be able to sue this result but should rather conduct their own HIV test at a DAIDS approved lab.

2. Provide your reasoning for your response.

   It is very essential that PI has enough oversight and sign all lab reports to make sure that there are no safety concerns for the patient. As the HIV result is not obtained from a DAIDS approved lab, these results cannot be considered for the study.

3. Miss Bandile Smith. is enrolled for a study. Protocol has mentioned the list of prohibited medications and protocol mentions that patients on NSAIDS are not eligible for the study.

14-April-2019

Bandile Smith
DOB 11 Feb 1999 Chart#1123

Bandile Smith is a 20-year-old girl with a medical history of hypothyroid. Below is the Ms. Smith's list of medical history and concomitant medications.

Past Medical History:

- Hypotension
- Moderate Obesity
- Hyperlipidaemia
- Headache

Medications:

- Ibuprofen 200 mg. po daily
- Lipitor 20 mg. po daily since 2019
- Thyronom 100 mg. daily since August 2018

1. Can this patient be enrolled in the study?

   Patient is taking Ibuprofen which is an NSAID. Hence the participant won't be able to participant in the study.

2. Is there enough data available for medical conditions and the concomitant medications mentioned in the above notes?

Start and stop dates are not mentioned about the medical conditions

3. Please mention your comments and discrepancies below. Also, provide your reasoning for your response.

   Complete information is required for the medical conditions and the concomitant medications. Any participant on prohibited medications cannot be included in the study.

4. Below is Miss. Bandile Smith's IVRS report.
   Miss. Bandil signed the ICF at 9 am on 14th April and the site coordinator then made the IVRS call. Has she performed the task according to GCP?

Screening Confirmation

Generated on: 14-Apr-2019 at 13:50 (BST)

Country: ZA

Site: 25

Investigator: KT Mgadi

Subject Number: 2503

Initials: BS

Date of Birth: 11-Feb-1964

Date of Screening: 14-Apr-2019

Local Date and Time of Call: 14-Apr-2019 07:50 (CDT)

IVRS Project Ref: A534

1. Identify the key issues in the below IVRS report?

   ICF has been signed before the screening assessments as per the time mentioned in the IVRS report. Date of birth is incorrect in the IVRS report

2. Provide your reasoning for your response

   It is essential that not any study related assessment is performed before the informed consent form is signed as per ICH GCP. Always make sure the information mentioned in the IVRS report is correct