

## Source Documents Activity

### Activity Title: To Enroll or not Enroll? The Case of 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  $\geq$  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
<p>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.</p>		
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

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

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

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## Source Documents Activity

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 _____		

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

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2. Provide your reasoning for your response.

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## Source Documents Activity

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
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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?

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

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

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## Source Documents Activity

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

<b>Screening Confirmation</b>	
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?

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2. Provide your reasoning for your response

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