
	Comprehension Test
	Date: 2023

SOP 33-1 COMPREHENSION TEST	
Instructions:	<p>This comprehension test refers to SOP 33-1.</p> <p>Each question is a multiple-choice question with three answer choices.</p> <p>Please read each question and answer choice carefully and choose the one best answer, ticking appropriate box.</p>


QUESTION n. 1	
When a site is responsible to communicate to AJCM/AMCL/CMCL/RMCL Device Deficiencies within 24 hours from the awareness?	
A. <input type="checkbox"/>	Only when lead to an Adverse Events
B. <input type="checkbox"/>	Only when lead to a Serious Adverse Events
C. <input checked="" type="checkbox"/>	Also when not lead to an adverse event but could have led to a medical occurrence, if either suitable action had not been taken or if intervention had not been made, or if circumstances had been less fortunate.

QUESTION n. 2	
The Sponsor shall identify, assess and control the risks associated with clinical investigation processes to ensure the ethical and scientific conduct of the clinical investigation and the credibility of the clinical investigation results. Which is the relevant reference procedure that the AJCL/AMCL/CMCL/RMCL has to follow?	
A. <input checked="" type="checkbox"/>	SOP 14-2
B. <input type="checkbox"/>	FRM 14-2
C. <input type="checkbox"/>	WIN 33-01-07


QUESTION n. 3	
What is the timelines for the completion of a Site Initiation Visit Report?	
A. <input checked="" type="checkbox"/>	5 working days from the visit
B. <input type="checkbox"/>	10 working days from the visit
C. <input type="checkbox"/>	10 days from the visit

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<b>QUESTION n. 4</b>
<b>When the Principal Investigator has to sign and date the Subject Identification Log?</b>
A. <input type="checkbox"/> At the beginning of the trial
B. <input checked="" type="checkbox"/> At the end of the trial
C. <input type="checkbox"/> Either ways, important it is signed

  
jaroslaw malski / 26 Apr 2023

<b>TOTAL SCORE</b>	<input type="checkbox"/>
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E: Non-Effective; PE: Partially Effective.

EFFECTIVENESS ASSESSMENT	
Notes:	
Corrective Actions (mandatory in case of NE or PE training)	
LAST NAME and First Name:	
Date:	Signature: