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

QUESTION n. 1	
When a site is responsible to communicate to AJCM/AMCL/CMCL/RMCL Device Deficiencies within 24 hours from the awareness?	
A. ☐	Only when lead to an Adverse Events
B. ☐	Only when lead to a Serious Adverse Events
C. ☒	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. ☒	SOP 14-2
B. ☐	FRM 14-2
C. ☐	WIN 33-01-07

QUESTION n. 3	
What is the timelines for the completion of a Site Initiation Visit Report?	
A. ☒	5 working days from the visit
B. ☐	10 working days from the visit
C. ☐	10 days from the visit

QUESTION n. 4	
When the Principal Investigator has to sign and date the Subject Identification Log?	
A. ☐	At the beginning of the trial
B. ☒	At the end of the trial
C. ☐	Either ways, important it is signed

TOTAL SCORE ☐

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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: