



Training and Education Sheet

no.: _____ year: 2025

REFERENCES

Title:	All Lima SOPs including the updated versions		
Objectives:	Understanding the contents of the new documentation (SOP, WINs and FRMs) in order to be in compliance with the new requirements of Regulation 2017/745 MDR and ISO 14155:2020 for clinical investigations.		
Subjects:	Contents of all documents (SOPs, WINs and FRMs)		
Operating Procedures / Instructions of ref.:	SOP 33-1 rev.3 "Clinical Investigation" + SOP 14-2 "Risk Management in Clinical Investigation" rev.0 + WINs and FRMs SOP 33-1 rev.3; SOP 14-2 rev.0; WIN 33-1-XX all and FRM 33-YY all. Including updated version All Lima templates and Forms		
Start/End Date:	04 June 2025 / 05 June 2025	Duration [hours]:	3
Teacher/s:	Last Name and First Name:.,:Self-Training		
	Signature: NA		

EFFECTIVENESS ASSESSMENT METHOD

<input checked="" type="checkbox"/> Pratical Test (attach) ⁽¹⁾
<input type="checkbox"/> Observation on the job ⁽¹⁾
<input type="checkbox"/> Written Test (attach)
<input type="checkbox"/> Interview
<input type="checkbox"/> Not required ⁽²⁾
⁽¹⁾ Describe the pratical test or the observation in the appropriate "Note" section
⁽²⁾ Exclusively for interventions of an informational nature or awareness interventions.



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Key: E=Effective; NE: Non-Effective; PE: Partially Effective.

PARTICIPANTS					
LAST NAME and First Name	Date	Signature	Effectiveness assessment		
			E	NE	PE
Bartosz Mikolajczak	05 Jun 2025	Bartosz Mikolajczak	X		

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