

	Training and Education Sheet	
	no.:	year: 2023

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:	26 Apr 2023	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⁾
<small>⁽¹⁾ Describe the pratical test or the observation in the appropriate "Note" section</small>
<small>⁽²⁾ Exclusively for interventions of an informational nature or awareness interventions.</small>

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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
jaroslaw malski	26 Apr 2023		X		

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