



Protocol Deviation Log

Protocol ID:	H-34	Principal Investigator:	Dr Jerzy Bialecki
Protocol short title:	Delta Revision CUP	Study site ID:	101
Study site name:	Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP	Country:	Poland

Site ID	Subject ID	Date of deviation (dd/mm/yyyy)	Category of deviation (Minor, major, critical)	Description of deviation	Reason for deviation and corrective measures taken	IRB/IEC Notification (yes/no)	Date of closure (dd/mm/yyyy)
101	101-02	30/JER/2021	MAJOR	THE DATE OF ICF SIGNATURE THE SITE STAFF WAS WRITTEN BY SI, NOT BY SUBJECT. WAS REMAINED		Y <input type="checkbox"/> N <input type="checkbox"/>	
101	101-03	11/OCT/2021	MAJOR	THE DATE OF ICF SIGNATURE THE SITE STAFF WAS WRITTEN BY SI, NOT BY SUBJECT. WAS REMAINED		Y <input type="checkbox"/> N <input type="checkbox"/>	
101	101-04	20/OCT/2021	MAJOR	ICF NOT SIGNED BY THE SUBJECT. THE DATE WRITTEN BY SI, NOT SUBJECT. SITE WAS REMAINED		Y <input type="checkbox"/> N <input type="checkbox"/>	03/PRP/2022
101	101-05	26/OCT/2021	MAJOR	THE DATE OF ICF SIGNATURE THE SITE STAFF WAS WRITTEN BY SI, NOT SUBJECT. WAS REMAINED		Y <input type="checkbox"/> N <input type="checkbox"/>	
101	101-06	25/OCT/2021	MAJOR	THE DATE OF ICF SIGNATURE THE SITE STAFF WAS WRITTEN BY SI, NOT SUBJECT. WAS REMAINED		Y <input type="checkbox"/> N <input type="checkbox"/>	
101	101-07	11/NOV/2021	MAJOR	THE DATE OF ICF SIGNATURE THE SITE STAFF WAS WRITTEN BY SI, NOT SUBJECT. WAS REMAINED		Y <input type="checkbox"/> N <input type="checkbox"/>	
101	101-07-101-15	08/NOV/2021	MAJOR	CONSENT PROCESS NOT DOCUMENTED	THE SITE WAS ALERTED TO PROVIDE SUPPLEMENTS.	Y <input type="checkbox"/> N <input type="checkbox"/>	04/NOV/2022
101	101-14	17/NOV/2022	MAJOR	DELAYED SAE REPORTING	THE SITE WAS ALERTED TO REPORT SAE WITHIN 24H	Y <input type="checkbox"/> N <input type="checkbox"/>	09/NOV/2022
101	101-07	20/NOV/2022	MINOR	OUT OF WINDOW VISIT	THE SITE STAFF REMINDS TO SCHEDULE THE VISITS AS PER PROTOCOL	Y <input type="checkbox"/> N <input type="checkbox"/>	09/NOV/2022
101	101-2	29/MAY/2022	MAJOR	6 MEV VISIT WAS NOT DONE	LACK OF CONTACT WITH PATIENT	Y <input type="checkbox"/> N <input type="checkbox"/>	29/MAY/2022
101	101-17	26/APR/2023	MAJOR	LATE SAE REPORTING	OMISSION	Y <input type="checkbox"/> N <input type="checkbox"/>	17/MAY/2023
						Y <input type="checkbox"/> N <input type="checkbox"/>	