

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/mmm/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/mmm/yyyy)
101	101-02	30/SEP/2021	MAJOR	THE DATE OF ICF SIGNATURE THE SITE STAFF WAS WRITTEN BY SJ, NOT SUBJECT. WAS RETAINED	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 SJ, NOT SUBJECT. WAS RETAINED	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 SJ, NOT SUBJECT. WAS RETAINED TO SIGN THE ICF	Y <input type="checkbox"/> N <input type="checkbox"/>	03/NOV/2021	
101	101-05	26/OCT/2021	MAJOR	THE DATE OF ICF SIGNATURE THE SITE STAFF WAS WRITTEN BY SJ, NOT SUBJECT. WAS RETAINED	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 SJ, NOT SUBJECT. WAS RETAINED	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 SJ, NOT SUBJECT. WAS RETAINED	Y <input type="checkbox"/> N <input type="checkbox"/>		
101	101-07-101-15	09/NOV/2021	MAJOR	CONSENT PROCESS NOT DOCUMENTED THE SITE WAS ASKED TO PROVIDE SUPPLEMENTAL	Y <input type="checkbox"/> N <input type="checkbox"/>	04/NOV/2021	
101	101-14	17/NOV/2021	MAJOR	PRELAYED SAE REPORTING THE SITE WAS ASKED TO REPORT SAES WITHIN 24H	Y <input type="checkbox"/> N <input type="checkbox"/>	08/NOV/2021	
101	101-07	20/NOV/2021	MINOR	OUT OF WINDOW VISIT THE SITE WAS ASKED TO SCHEDULED	Y <input type="checkbox"/> N <input type="checkbox"/>	04/NOV/2021	
				THE VISIT AS PER PROTOCOL	Y <input type="checkbox"/> N <input type="checkbox"/>		
101	101-2	29/MAY/2022	MAJOR	6 MFU 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"/>		