



# Protocol Deviation Log

<b>Protocol ID:</b>	H-34	<b>Principal Investigator:</b>	Dr Jerzy Białecki
<b>Protocol short title:</b>	Delta Revision CUP	<b>Study site ID:</b>	101
<b>Study site name:</b>	Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP	<b>Country:</b>	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 OF ICF WRITTEN BY SI, NOT BY SUBJECT. SITE WAS REMAINED		Y <input type="checkbox"/> N <input type="checkbox"/>	03/PRAP/2022
101	101-05	26/OCT/2022	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	101-07-101-16	09/JUN/2022	MAJOR	CONSENT PROCESS NOT DOCUMENTED	THE SITE WAS ASKED TO PROVIDE SUPPLEMENT	Y <input type="checkbox"/> N <input type="checkbox"/>	04/NOV/2022
101	101-14	17/JUN/2022	MAJOR	DELAYED SAE REPORTING	THE SITE WAS ASKED TO REPORT SAE WITHIN 24H	Y <input type="checkbox"/> N <input type="checkbox"/>	09/NOV/2022
101	101-07	20/JUN/2022	MINOR	OUT OF WINDOW VISIT	THE SITE STAFF REMINDERS TO SCHEDULE THE VISITS AS PER PROXY	Y <input type="checkbox"/> N <input type="checkbox"/>	09/NOV/2022
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"/>	23/MAY/2022
101	101-17	26/APR/2023	MAJOR	LATE SAE REPORTING	OMISSION	Y <input type="checkbox"/> N <input type="checkbox"/>	17/MAY/2023
101	101-24	08/MAR/2024	MAJOR	DELAYED VISIT OUT OF WINDOW	PATIENT COULDN'T / NOT AVAILABLE TO COME	Y <input type="checkbox"/> N <input type="checkbox"/>	21/MAR/2024

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