

## Protocol Deviation Log

|   |  |  |  |
|---|--|--|--|
|  |  |  |  |
|---|--|--|--|

|                              |  |                                |                   |
|------------------------------|--|--------------------------------|-------------------|
| <b>Protocol ID:</b>          | H-34   | <b>Principal Investigator:</b> | Dr Jerzy Bialecki |
| <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<br>(dd/mmm/yyyy) | Category of deviation<br>(Minor, major, critical) | Description of deviation  | Reason for deviation and corrective measures taken       | IRB/IEC Notification<br>(yes/no)                      | Date of closure<br>(dd/mmm/yyyy) |
|---------|---------------|------------------------------------|---|---|--|---|----------------------------------|
| 101     | 101-02        | 30/JUL/2021                        | MAJOR   | THE DATE OF ICF SIGNATURE THE SITE STAFF WAS WRITTEN BY SJ, NOT SUBJECT, WAS RETAINED | THE SITE STAFF 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 | THE SITE STAFF WAS RETAINED                              | Y <input type="checkbox"/> N <input type="checkbox"/> |                                  |
| 101     | 101-04        | 20/OCT/2021                        | MAJOR   | IF NOT SIGNED BY THE SUBJECT THE DATE WRITTEN BY SJ, NOT SUBJECT SITE 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 WRITTEN BY SJ, NOT SUBJECT WAS RETAINED      | THE SITE STAFF 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 WRITTEN BY SJ, NOT SUBJECT WAS RETAINED      | THE SITE STAFF 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 WRITTEN BY SJ, NOT SUBJECT WAS RETAINED      | THE SITE STAFF WAS RETAINED                              | Y <input type="checkbox"/> N <input type="checkbox"/> |                                  |
| 101     | 101-07-101-18 | 09/NOV/2021                        | MAJOR   | CONSENT PROCESS NOT DOCUMENTED THE SITE WAS ASKED TO PROVIDE SUPPLEMENT               | THE SITE WAS ASKED TO PROVIDE SUPPLEMENT                 | Y <input type="checkbox"/> N <input type="checkbox"/> | 09/NOV/2021                      |
| 101     | 101-19        | 17/NOV/2021                        | MAJOR   | DELAYED SOE REPORTING THE SITE WAS ASKED TO REPORT SOEs WITHIN 24h                    | THE SITE WAS ASKED TO REPORT SOEs WITHIN 24h             | Y <input type="checkbox"/> N <input type="checkbox"/> | 09/NOV/2021                      |
| 101     | 101-07        | 20/NOV/2021                        | MINOR   | OUT OF WINDOW VISIT   | THE SITE WAS ASKED TO SCHEDULE THE VISIT AS PER PRACTICE | Y <input type="checkbox"/> N <input type="checkbox"/> | 09/NOV/2021                      |
| 101     | 101-2         | 29 MAY 2022                        | MAJOR   | 6 HFU 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 SOE 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 COULDNT NOT AVAILABLE TO COME                    | Y <input type="checkbox"/> N <input type="checkbox"/> | 21 MAR 2024                      |



## Protocol Deviation Log