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| **Serial number**  | **Deviation brief description**  | **Deviation category**  | **Date deviation occurred** **Dd/mm/yyyy** | **Date investigators became aware of** **Dd/mm/yyyy** | **Corrective action**  | **Date reported to ERB if applicable** | **Patient continuation in trial after deviation identified** **1 yes****2 No. patient withdrew by investigators**  | **PI initials**  |
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**Deviation category**

1. Consent document and process
2. Screening
3. Interventions
4. Randomization
5. Visit schedules /follow up
6. Investigational product IP management
7. Safety reporting and Data management
8. Others specify \_\_\_\_\_\_\_\_\_\_\_

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| --- | --- | --- | --- |
| **Consent**  | **Screening**  | **Interventions**  | **Randomization**  |
| * Most recent ERB-approved consent document not used
* Consent not obtained before initiating study procedures
* consent document not appropriately signed/dates missing
* Wrong version of consent form used
* consent taken by unauthorized person (not on delegation of authority log
* Others specify \_\_\_\_\_\_\_\_\_\_
 | * Inclusion criteria not met but participant was enrolled
* Exclusion criteria was not met but participant was enrolled
* Screening Performa incomplete unsigned or unstamped
* Required eligibility labs or assessments missed before enrollment
* Others specify \_\_\_\_\_\_\_\_\_
 | * Wrong treatment given (not per allocation/randomization)
* Wrong intervention performed
* Missed dose of investigational product
* Study intervention not followed as per protocol schedule
* Required procedures/ labs/interventions missed
* Others specify \_\_\_\_\_\_\_\_\_\_\_
 | * Randomization performed before informed consent
* Participant randomized despite failing eligibility criteria
* Incorrect randomization code used
* Allocation envelope opened out of sequence
* Wrong participant ID entered into randomization system
* Randomization performed outside the permitted time window
* Others specify \_\_\_\_\_\_\_\_\_\_\_\_\_
 |
| **Visit schedules / follow up** | **Investigational product IP management**  | **Safety reporting and data management**  | **Others**  |
| * Participants missed scheduled visit
* Visit conducted outside protocol-defined time window
* Unscheduled visits not documented in the protocol
* Visits specific tasks / procedures / labs not performed
 | * Incorrect storage temperature or conditions
* IP dispensed without proper documentation
* IP accountability records incomplete or inaccurate
* IP dispensed to wrong treatment
 | * Adverse event not reported within required timeline
* SAE form incomplete or missing
* Missing documentation for safety follow-up assessments
* Case Report Form (CRF) incomplete or inconsistent with source documents
* Source documents missing or not updated in real time
* Data entry errors identified after monitoring
* Others specify \_\_\_\_\_\_\_\_\_\_\_\_
 | Specify  |