PUSAT KOMPLIANS DAN KAWALAN KUALITI
CENTRE OF COMPLIANCE AND QUALITY CONTROL

BAHAGIAN REGULATORI FARMASI NEGARA
NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA)

KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

Serious Breach Report

Please forward this serious breach report to mygcp@npra.gov.my

Section 1: Trial Information	
Protocol No.	
Protocol Title	
National Medical Research Register (NMRR) Number	
CTIL/CTX Number	
CTIL/CTX Holder's Name and Organisation Details	
Name of Sponsor	
Section 2: General Information	
Initial Report	☐
Follow-up Report	☐
Follow-up Report Number (number the follow-up reports sequentially, starting from 01)	
Status of the investigation of the serious breach	☐ Concluded ☐ Ongoing Estimated date of next follow-up (if known):
Date of Occurrence of Serious Breach	
Date Serious Breach Identified by Sponsor	
Date Serious Breach notified by Sponsor to CRO (if applicable)	
Date Initial Serious Breach reported to NPRA	
Details of the site where the serious breach occurred	
Affected countries	
Category	☐ Adverse event reporting ☐ Informed consent ☐ Investigational product ☐ Randomisation and blinding ☐ Source documentation ☐ Study conduct ☐ Use of unapproved documents ☐ Others (to specify): _____

Area(s) impacted by the Serious Breach	☐ Subject rights ☐ Subject safety ☐ Subject well-being ☐ Data reliability or robustness ☐ Regulatory ☐ Others (to specify): _____
Are other clinical trials impacted by the same serious breach?	☐ No ☐ Not Known ☐ Yes If yes, please specify the Protocol Number, CTIL/CTX and NMRR number: *(The reporter is requested to indicate in this section if they are aware of other clinical trial(s), registered with the NMRR, impacted by the same serious breach)*

Section 4: Details of the Serious Breach
Brief description of the serious breach:
Potential impact of the serious breach: *(in addition to the areas impacted by the serious breach which are mentioned above, please indicate the sub-category (e.g. consent form/confidentiality/IMP/approval issues, etc.)*
Other relevant information/details:
Section 5: Details of the action(s) taken/planned *For each of the following sub-sections, if details are not known at the time of reporting, a statement should be included indicating when the information will be available and submitted as a follow-up report.*
Impact Assessment: *(the extent of the breach and its impact should be investigated and reported. Please provide comprehensive details of the impact assessment, including what has been assessed, and the methodology used to conduct the assessment.)*
Root Cause Investigation(s): *(describe the root cause investigation and results/outcomes of the investigation)*

Corrective and Preventive Action (CAPA) Plan: *(CAPA plan should outline any actions already taken. For each action, the following details should be provided: the responsible party for the action (sponsor, CRO, CRA, site personnel, etc.), the implementation timeline, and whether the action has already concluded or is still pending. The CAPA plan should also describe how this incident will be documented in the Trial Master File (TMF):*
Actual Impact: *(the actual consequences of the serious breach should be reported, including whether the action partially or totally prevented the "potential impact" (reported above) from occurring and indicate if corrective actions can still be implemented to ensure the safety of the affected trial participants, or to ensure the reliability of the data).*

Declaration by CTIL/CTX Holder	
I, the undersigned, hereby declare and confirm that: 1. The information provided in this Serious Breach Report and any accompanying documents is true, accurate, and complete to the best of my knowledge and belief at the time of submission. 2. I understand that it is my responsibility, as the CTIL/CTX Holder, to ensure compliance with the Principles of Good Clinical Practice and the applicable regulatory requirements. 3. I undertake to promptly provide any additional information or clarification requested by the regulatory authority and to notify the authority of any further developments related to this serious breach.	
Signature of CTIL/CTX Holder	
Full Name	
Designation in the Company / Organisation	
Date (DD/MMM/YYYY)	