**Complete and return this form to:**

**pharmaco@abdn.ac.uk**

**For guidance please refer to SOP-QA-25**

|  |
| --- |
| **Please report for:**1. **any events that could have led to harm or could have been prevented by a change of process and not reported as a serious adverse event;**

 **or**1. **any breaches of trial protocol or Good Clinical Practice.**
 |

|  |  |
| --- | --- |
| **Protocol title:** |  |
| **Chief Investigator:** | **Sponsor Ref:** |
| **EudraCT No (if applicable):** | **REC Ref:** |
| **Date of Incident:**  | **Site breach occurred:** |
| **Date reported to trial staff:** |
| **Name and contact details of person reporting breach to Sponsor:** |

**Detail of the breach (please specify if a patient safety and/or data integrity and/or data protection issue):**

**Corrective and Preventive Action Implemented (CAPA) by Trial Staff:**

|  |
| --- |
| ***FOR OFFICE USE ONLY*** |
| **Date Breach Report received:** | **Date of Breach Assessment:** |
| **Serious Breach:** | **❒** | **Non-Serious Breach:** | **❒** |
| **Date of notification to REC:** | **Reported by:** |
| **Date of notification to DP/IG Team:** ***(if applicable)*** | **Reported by:*****(if applicable)*** |
| **Date of notification to MHRA:*****(if applicable)*** | **Reported by:*****(if applicable)*** |
| **For Serious Breach CAPA, please refer to assessment report** |