**Complete and return this form to:**

[**pharmaco@abdn.ac.uk**](mailto: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** | | | |