

**Log of Breaches and Urgent Safety Measures**

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| **Study Title:** |  | **EudraCT Number:**  |  | **CI:** |  |
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| **Site Name and Address:** |  |

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| **Date incident added to log** | **Incident date** | **Participant number** | **Non-serious Breach, Serious Breach or Urgent Safety Measure (USM)** | **Site corrective action** | **Site preventive action** | **Date reported to Sponsor** | **Urgent Safety Measure reported to MHRA, REC, R&D QA** |
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