Incident Report

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| --- | --- |
| **Organisation name:** |  |
| **Trial(s) affected:** |  |
| **Trial number(s) of affected patients *(if applicable)*** |  |
| **Name of IMP affected *(if applicable)*** |  |
| Details of the incident: *(Include date(s) incident occurred, how/when it was identified, why it occurred and, where applicable, trial numbers of patient(s) affected and IMP(s) affected)* | |
| **Corrective action:**  *(Detail measures that were taken to address the incident and/or minimise its impact. Include date(s) of implementation/planned implementation and person(s) responsible)* | |

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| **Preventative action:**  *(Detail measures that have been or that will be implemented to prevent future occurrences. Include date(s) of implementation/planned implementation and person(s) responsible)* |

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| **Form completed by:** | | | |
| **Name:** |  | **Job title:** |  |
| **e-mail:** |  | **Tel no:** |  |
| **Signature:** |  | **Date:** |  |

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| **Date received:** |  |
| **Reviewed by:** |  |
| **For all incidents meeting criteria for referral or discussion per SOP T69:** | |
| **Potential serious breach/urgent safety measure?** | **Yes** *If yes, add details in Comments box below*  **No** |
| **Requires referral**  **to Regulatory?** | **Yes**  **No** |
| **Requires referral**  **to Stats?** | **Yes**  **No** |
| **Date discussed with STC /TGL** |  |
| **Comments:** | |
|  | |
| **PLEASE ENTER DETAILS ON TRIAL INCIDENT LOG FOR ALL TRIAL(S) AFFECTED & FILE REPORT IN APPROPRIATE TMF(S)** | |