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| Deviation Reporting Spot Check |
| **Short Study Title:** |  |
| **Chief Investigator (CI):** |  |
| **Study Identifier:****(IRAS Ref)** |  |
| **Date of Spot Check:** |  |

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| Compliance Summary |
| **Number of Locations Spot Checked:** |  |
| **Location Compliance Level:** | **Red (add no. of locations):**  |  |
| **Amber (add no. of locations):** |  |
| **Green (add no. of locations):** |  |
| **\*Overall Compliance Level (Red/Amber/Green):** |  |
| **Recommendations for Action:** | **[Delete as appropriate as agreed with QA Coordinator/Manager]*** Please remind all PIs / locations of the importance of protocol compliance in terms of deviation reporting in accordance with the trial protocol.
* Please contact the following PIs / locations regarding the importance of protocol compliance in terms of deviation reporting in accordance with the trial protocol.

**[insert trial locations(s)]*** Please advise on any further action instigated and deemed appropriate by the Trial Manager and/or CI.
* Sponsor QA/Monitoring team to determine if a monitoring visit is required for **[insert location(s)]**.
 |
| **Sign On Completion** |
| **Quality Assurance Administrator:** |  |
| **QA Manager or QA Coordinator:** |  |

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| **[ADD LOCATION NAME/NUMBER and SATO date]** |
| **Is the location compliant with Protocol Deviation Reporting Requirements?** | [ADD QUARTER][ADD YEAR] | [ADD QUARTER][ADD YEAR] | [ADD QUARTER][ADD YEAR] | [ADD QUARTER][ADD YEAR] |
| **[ ]** No **[ ]** Yes **[ ]** N/A   | **[ ]** No **[ ]** Yes **[ ]** N/A   | **[ ]** No **[ ]** Yes **[ ]** N/A   | **[ ]** No **[ ]** Yes **[ ]** N/A  |
| **If ‘NO’, is there email confirmation that no Deviations were reported in this Quarter?** | **[ ]** No **[ ]** Yes **[ ]** N/A | **[ ]** No **[ ]** Yes **[ ]** N/A | **[ ]** No **[ ]** Yes **[ ]** N/A | **[ ]** No **[ ]** Yes **[ ]** N/A |
| **Location Compliance Level:** | 100% (Green) **[ ]** 75% (Green) **[ ]** 50% (Amber) **[ ]**  25% (Amber) **[ ]** 0% (Red) **[ ]**  |

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| **[ADD LOCATION NAME/NUMBER and SATO date]** |
| **Is the location compliant with Deviation Reporting Requirements?** | [ADD QUARTER][ADD YEAR] | [ADD QUARTER][ADD YEAR] | [ADD QUARTER][ADD YEAR] | [ADD QUARTER][ADD YEAR] |
| **[ ]** No **[ ]** Yes **[ ]** N/A   | **[ ]** No **[ ]** Yes **[ ]** N/A  | **[ ]** No **[ ]** Yes**[ ]** N/A   | **[ ]** No **[ ]** Yes**[ ]** N/A   |
| **If ‘NO’, is there email confirmation that no Deviations were reported in this Quarter?** | **[ ]** No **[ ]** Yes **[ ]** N/A | **[ ]** No **[ ]** Yes **[ ]** N/A | **[ ]** No **[ ]** Yes **[ ]** N/A | **[ ]** No **[ ]** Yes **[ ]** N/A |
| **Location Compliance Level:** | 100% (Green) **[ ]** 75% (Green) **[ ]** 50% (Amber) **[ ]**  25% (Amber) **[ ]** 0% (Red) **[ ]**  |

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| --- |
| **[ADD LOCATION NAME/NUMBER and SATO date]** |
| **Is the location compliant with Protocol Deviation Reporting Requirements?** | [ADD QUARTER][ADD YEAR] | [ADD QUARTER][ADD YEAR] | [ADD QUARTER][ADD YEAR] | [ADD QUARTER][ADD YEAR] |
| **[ ]** No **[ ]** Yes **[ ]** N/A   | **[ ]** No **[ ]** Yes **[ ]** N/A   | **[ ]** No **[ ]** Yes **[ ]** N/A   | **[ ]** No **[ ]** Yes **[ ]** N/A  |
| **If ‘NO’, is there email confirmation that no Deviations were reported in this Quarter?** | **[ ]** No **[ ]** Yes **[ ]** N/A | **[ ]** No **[ ]** Yes **[ ]** N/A | **[ ]** No **[ ]** Yes **[ ]** N/A | **[ ]** No **[ ]** Yes **[ ]** N/A |
| **Location Compliance Level:** | 100% (Green) **[ ]** 75% (Green) **[ ]** 50% (Amber) **[ ]**  25% (Amber) **[ ]** 0% (Red) **[ ]**  |

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| --- |
| **[ADD LOCATION NAME/NUMBER and SATO date]** |
| **Is the location compliant with Protocol Deviation Reporting Requirements?** | [ADD QUARTER][ADD YEAR] | [ADD QUARTER][ADD YEAR] | [ADD QUARTER][ADD YEAR] | [ADD QUARTER][ADD YEAR] |
| **[ ]** No **[ ]** Yes **[ ]** N/A   | **[ ]** No **[ ]** Yes **[ ]** N/A   | **[ ]** No **[ ]** Yes **[ ]** N/A   | **[ ]** No **[ ]** Yes **[ ]** N/A  |
| **If ‘NO’, is there email confirmation that no Deviations were reported in this Quarter?** | **[ ]** No **[ ]** Yes **[ ]** N/A | **[ ]** No **[ ]** Yes **[ ]** N/A | **[ ]** No **[ ]** Yes **[ ]** N/A | **[ ]** No **[ ]** Yes **[ ]** N/A |
| **Location Compliance Level:** | 100% (Green) **[ ]** 75% (Green) **[ ]** 50% (Amber) **[ ]**  25% (Amber) **[ ]** 0% (Red) **[ ]**  |

**[ADD/DELETE ADDITIONAL TABLES BASED ON THE NUMBER OF LOCATIONS TO CHECK.]**