**DIRECTORATE OF RESEARCH AND INNOVATION**

**Study Amendment Tracker**

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| --- | --- |
| **R&D Number:** |  |
| **Short Title of Study:** |  |
| **Principal Investigator (PI):** |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Number** | **Amendment description and rationale**  *(as per cover letter/amendment form)* | **Documents updated and new version numbers** *(often found in approval letters)* | **Substantial or Non-Substantial?**  *(dates are in cover letters/approval letters)* | **Has relevant training been completed and documented?** | **Person completing tracker** | |
| **Name** | **Date** |
|  |  |  | **Substantial**   |  |  |  | | --- | --- | --- | |  | Date informed | Date approved | | R&D | DD-MMM-YYYY | DD-MMM-YYYY | | MHRA | DD-MMM-YYYY  or NA | DD-MMM-YYYY  or NA | | REC | DD-MMM-YYYY  or NA | DD-MMM-YYYY  or NA | | HRA | DD-MMM-YYYY | DD-MMM-YYYY |   **Non-Substantial**   |  |  |  | | --- | --- | --- | |  | Date informed | Date approved | | HRA | DD-MMM-YYYY | DD-MMM-YYYY | | R&D | DD-MMM-YYYY | DD-MMM-YYYY | | **Y/N** |  | DD-MMM-YYYY |
|  |  |  | **Substantial**   |  |  |  | | --- | --- | --- | |  | Date informed | Date approved | | R&D | DD-MMM-YYYY | DD-MMM-YYYY | | MHRA | DD-MMM-YYYY  or NA | DD-MMM-YYYY  or NA | | REC | DD-MMM-YYYY  or NA | DD-MMM-YYYY  or NA | | HRA | DD-MMM-YYYY | DD-MMM-YYYY |   **Non-Substantial**   |  |  |  | | --- | --- | --- | |  | Date informed | Date approved | | HRA | DD-MMM-YYYY | DD-MMM-YYYY | | R&D | DD-MMM-YYYY | DD-MMM-YYYY | | **Y/N** |  | DD-MMM-YYYY |