# Pharmacy Assurance: Amendment Site Notification Form

This form may be completed by Sponsors and sent to participating sites to inform them of amendments which will affect the content of the Pharmacy Technical Review Form. It is not a requirement and if completed it is only necessary to include information in the relevant sections. It may also be used to inform sites of other information which may affect pharmacy departments’ capacity and capability to conduct the trial. Some examples of situations where this may be required are available on the [IRAS website](https://www.myresearchproject.org.uk/help/hlppharmacyassurance594.aspx).

## Study Identification (To be completed by Sponsor)

|  |  |
| --- | --- |
| **IRAS ID** |  |
| **EudraCT Number** |  |
| **Study Title** |  |
| **Sponsor** |  |
| **Amendment Version Number and Date** |  |
| **Does this amendment add or remove a treatment arm? If yes, which ones?** |  |
| **Does this amendment add or remove an Investigational Medicinal Product (IMP) / Auxiliary Medicinal Product (AMP)? If yes, which ones?** |  |

Amended Documents

|  |  |  |
| --- | --- | --- |
| **Document Name** | **New Version Number** | **New Date** |
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Insert additional rows as required.

## Pharmacy Amendment Details (To be completed by Sponsor)

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| **Area of Review Form** | **Previous Information** | **New Information** |
| Section 6: Pharmacy Resources  Include information about dispensing and treatment schedules |  |  |
| Section 7: Treatment Allocation / Randomisation / Blinding |  |  |
| Section 8: Emergency Unblinding |  |  |
| Section 9: General Funding  In particular include information about funding implications such as excess treatment costs and exit strategies |  |  |
| Section 10: Further Information on the Study  Include information about changes to BSA or GFR and blood test validity periods |  |  |
| Section 11.1: Product Information  In particular, include detail on:   * IMP / AMP name change * License status * Dose banding and capping procedures * Source of the IMP / AMP * Packaging of the IMP / AMP * Storage conditions and space required * Preparation / reconstitution of the IMP / AMP and subsequent storage * Product labels * Accountability * Receipt and re-ordering * Stock control * Disposal requirements * Formulation / manufacturing changes   Insert new rows for additional product information if required |  |  |
| Section 12: Additional information  Give details on any other information given in the original review which may affect pharmacy departments as a result of this amendment. |  |  |