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| --- |
| **Summary of Study: Set up, Population, Inclusion/Exclusion, Duration** |
| **Trial Design:**  **Planned duration:** |
| **Intervention:** |
| **IMP (± Placebo):**  **nIMPs:**  **Visit/Dispensing schedule:** |

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| **Impact for Directorate:** | |
| **Expected Workload:**  **IMP Supply and Storage:**  **End of trial arrangements:** | |
| **Funding and Costings (Pharmacy to complete):**  For commercially sponsored trials all pharmacy fees are fixed annually and should be incorporated into the contract or authorisation will not be granted.  For non-commercially sponsored trials pharmacy costs will be negotiated based on grant allocation for pharmacy services available. | |
| **Set up Fee:** |  |
| **IMP Annual Management Fee:** |  |
| **Dispensing fee (per patient per visit):** |  |
| **Prescription charge:** |  |
| **Delivery of IMP:** |  |
| **Other services – please specify:** |  |

**Directorate Authorisation**

|  |  |
| --- | --- |
|  | Name and Date |
| Approved |  |
| Approved pending some issues: |  |
| Not Approved – reasons below: |  |