**UHL Pharmacy Visit Report**

**Site Information**

|  |  |
| --- | --- |
| Study title: |  |
| Sponsor reference number: |  |
| Centre name: |  |
| Principal Investigator name: |  |
| Date of report |  |
| Date Response Due Back: |  |

**Study Overview**

|  |  |
| --- | --- |
| Items discussed/verified | Comment |
| Study IMP/s |  |

**Training Log**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | N/A | Comment |
| Signature log |  |  |  |  |
| **Comment/Findings:** | | | | |
|  | | | | |

**Contact Details**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | N/A | Comment |
| Contact details |  |  |  |  |
| **Comments/Findings:** | | | | |
|  | | | | |

**1. Synopsis**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | N/A | Comment |
| Study synopsis |  |  |  |  |
| Document version control history |  |  |  |  |
| **Comments/Findings:** | | | | |
|  | | | | |

**2. Dispensing**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | N/A | Comment |
| Dispensing procedure |  |  |  |  |
| Pre-printed labels |  |  |  |  |
| **Comments/Findings:** | | | | |
|  | | | | |

**3. Drug Accountability**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | N/A | Comment |
| Inventory logs |  |  |  |  |
| Patient specific |  |  |  |  |
| Masters |  |  |  |  |
| **Comments/Findings:** | | | | |
|  | | | | |

**4. Prescriptions/Worksheets**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | N/A | Comment |
| Completed |  |  |  |  |
| Master |  |  |  |  |
| **Comments/Findings:** | | | | |
|  | | | | |

**5. Order and Receipt**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | N/A | Comment |
| Procedure |  |  |  |  |
| Order |  |  |  |  |
| Receipt |  |  |  |  |
| Certificate of authorisation/QP release certificates |  |  |  |  |
| Re-labelling |  |  |  |  |
| **Comments/Findings:** | | | | |
|  | | | | |

**6. Returns/Destruction**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | N/A | Comment |
| Procedure |  |  |  |  |
| Documentation |  |  |  |  |
| **Comments/Findings:** | | | | |
|  | | | | |

**7. Code Break Information**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | N/A | Comment |
| Unblinding procedure and paperwork |  |  |  |  |
| Completed unblinding paperwork |  |  |  |  |
| **Comments/Findings:** | | | | |
|  | | | | |

**8. Pharmacy Personnel**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | N/A | Comment |
| CVs and GCP certificates |  |  |  |  |
| Trial specific training documentation |  |  |  |  |
| **Comments/Findings:** | | | | |
|  | | | | |

**9. Temperature Monitoring**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | N/A | Comment |
| Temperature monitoring file note |  |  |  |  |
| Temperature deviation information |  |  |  |  |
| Remote storage monitoring information |  |  |  |  |
| **Comments/Findings:** | | | | |
|  | | | | |

**10. Correspondence**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | N/A | Comment |
| Monitoring log and reports |  |  |  |  |
| Correspondence |  |  |  |  |
| **Comments/Findings:** | | | | |
|  | | | | |

**11. Regulatory Documentation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | N/A | Comment |
| Amendment documentation |  |  |  |  |
| Original approvals |  |  |  |  |
| Completed pharmacy risk assessment |  |  |  |  |
| Remote storage risk assessment documentation |  |  |  |  |
| Completed clinical trials review form |  |  |  |  |
| Completed folder audit forms |  |  |  |  |
| **Comments/Findings:** | | | | |
|  | | | | |

**12. Finance**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | N/A | Comment |
| Information |  |  |  |  |
| Fee structure and finance contract |  |  |  |  |
| Invoices |  |  |  |  |
| **Comments/Findings:** | | | | |
|  | | | | |

**13. Protocol**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items discussed/verified | Yes | No | N/A | Comment |
| Protocol |  |  |  |  |
| Pharmacy manual |  |  |  |  |
| **Comments/Findings:** | | | | |
|  | | | | |

**14. Investigator Brochure/SPCs**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items discussed/verified | Yes | No | N/A | Comment |
| Investigator Brochure |  |  |  |  |
| SPCs |  |  |  |  |
| **Comments/Findings:** | | | | |
|  | | | | |

**15. Superseded Pharmacy Documents**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items discussed/verified | Yes | No | N/A | Comment |
| Superceded documents |  |  | ☐ |  |
| **Comments/Findings:** | | | | |
|  | | | | |

**Additional Comments/ Visit Overview**

**Pharmacy Monitoring Visit Response Document**

**UHL Sponsor Reference Number:**

**Monitoring visit Date: Monitoring visit report date: Date response required:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Outstanding Issue** | **Action required** | **Action Taken** | **Date** |
|  |  |  |  |
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**Report Response Completed By:**

|  |
| --- |
| Name : |
| Telephone: |
| e-mail: |
| Signature: |
| Date: |

**Monitoring Report Completed By:**

|  |
| --- |
| Monitor : |
| Telephone |
| e-mail: |
| Signature: |
| Date: |

**Completed Responses Approved by PI:**

|  |
| --- |
| PI Name: |
| PI Signature: |
| Date: |

**Completed Monitoring Report Approved by:**

|  |
| --- |
| Monitor : |
| Signature: |
| Date Monitoring Report Closed: |