**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:**

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| --- |
| 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:  |