**UHL Pharmacy Initial Visit Checklist**

**Site Information**

|  |  |
| --- | --- |
| **Site** | **Initiation Visit Method** |
| Sponsor Reference Number: | On Site |
| Study Name: | Teleconference |
| Study Phase: | Other (specify) |
| Investigator: |  |
| Study Site: |  |
| Date of Initiation: |  |
| Conducted by: | |

**Personnel in Attendance**

|  |  |
| --- | --- |
| Name | Title |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Study Overview**

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

**Training Log**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Signature log |  |  |  |

**Contact Details**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Contact details |  |  |  |

**1. Synopsis**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Study synopsis |  |  |  |
| Document version control history |  |  |  |

**2. Dispensing**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Dispensing procedure |  |  |  |
| Labelling/ over-labelling |  |  |  |
| Master label |  |  |  |

**3. Drug Accountability**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Master inventory log |  |  |  |
| Master patient specific log |  |  |  |

**4. Prescriptions/Worksheets**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Master |  |  |  |

**5. Order and Receipt**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Procedure |  |  |  |
| Order |  |  |  |
| Receipt |  |  |  |
| C of A/QP release certificates |  |  |  |
| Re-labelling |  |  |  |

**6. Returns/Destruction**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Procedure |  |  |  |
| Documentation |  |  |  |

**7. Code Break Information**

|  |  |  |  |
| --- | --- | --- | --- |
| Items discussed/verified | Yes | No | Comment |
| Unblinding procedure and paperwork |  |  |  |

**8. Pharmacy Personnel**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Location of CVs and GCP certificates |  |  |  |
| Trial specific training documentation |  |  |  |

**9. Temperature Monitoring**

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

**10. Correspondence**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Monitoring log and reports |  |  |  |
| Correspondence |  |  |  |

**11. Regulatory Documentation**

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

**12. Finance**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Information |  |  |  |
| Fee structure and finance contract |  |  |  |

**13. Protocol**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items discussed/verified | Yes | No | N/A | Comment |
| Protocol |  |  |  |  |
| Pharmacy manual |  |  |  |  |

**14. Investigator Brochure/SmPCs**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items discussed/verified | Yes | No | N/A | Comment |
| Investigator Brochure |  |  |  |  |
| SmPCs |  |  |  |  |

**15. Superseded Pharmacy Documents**

|  |  |  |  |
| --- | --- | --- | --- |
| Items discussed/verified | Yes | No | Comment |
| Superseded documents |  |  |  |

**Additional Comments/ Visit Overview**

**SIV Completed By:**

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

**Report Responses Completed By:**

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

**Completed Responses Approved by PI:**

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

**Completed SIV Report Approved/ Closed By:**

|  |
| --- |
| Name: |
| Role: |
| Signature: |
| Date: |

UHL Site Initiation Final Outstanding Issue Sign Off

**Sponsor Reference and Short Title:**

**Date of Visit: Date of Report: Date Responses Due Back:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Outstanding Issue** | **Action required** | **Action Taken** | **Signature & Date** |
|  |  |  |  |  |
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