

UoL Pharmacy Initial Visit Checklist

1. Site Information

Site	Initiation Visit Method		
Sponsor Reference Number:		On Site	<input type="checkbox"/>
Study Name:		Teleconference	<input type="checkbox"/>
R&I Reference Number:		Other (specify)	<input type="checkbox"/>
Investigator:			
Study Site:			
Date of Initiation:			
Conducted by:			

2. Sponsor Personnel in Attendance

Name	Title

3. Study Overview

Items discussed/verified	Comment
Study IMP/s	

4. Training Log

Items Discussed/verified	Yes	No	Comment
Signature Log			

6. Contact Details

Items Discussed/verified	Yes	No	Comment
Contact Details			

7. Synopsis

Items Discussed/verified	Yes	No	Comment
Study Synopsis			
Document version control history			

8. Dispensing

Items Discussed/verified	Yes	No	Comment
Dispensing procedure			
Pre-printed labels			

9. Drug Accountability

Items Discussed/verified	Yes	No	Comment
Inventory Logs			
Patient Specific			
Masters			

10. Prescriptions/Worksheets

Items Discussed/verified	Yes	No	Comment
Completed			
Master			

11. Order and Receipt

Items Discussed/verified	Yes	No	Comment
Procedure			
Order			
Receipt			
C of A/QP Release Certificates			
Re-labelling			

12. Returns/Destruction

Items Discussed/verified	Yes	No	Comment
Procedure			
Documentation			

13. Code Break Information

Items discussed/verified	Yes	No	Comment
Unblinding Procedure and Paperwork			
Completed Unblinding Paperwork			

14. Pharmacy Personnel

Items Discussed/verified	Yes	No	Comment
CVs and GCP Certificates			
Trial Specific Training Documentation			

15. Temperature Monitoring

Items Discussed/verified	Yes	No	Comment
Temperature Monitoring File Note			
Temperature Deviation Information			
Remote Storage Monitoring Information			

16. Correspondence

Items Discussed/verified	Yes	No	Comment
Monitoring Log and Reports			
Correspondence			

17. 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			

18. Finance

Items Discussed/verified	Yes	No	Comment
Information			
Fee Structure and Finance Contract			
Invoices			

19. Protocol

Items discussed/verified	Yes	No	Comment
Protocol			
Pharmacy Manual			

20. Investigator Brochure/SPCs

Items discussed/verified	Yes	No	Comment
Investigator Brochure			
SPCs			

21. Superseded Pharmacy Documents

Items discussed/verified	Yes	No	Comment
Superseded Documents			

Additional Comments/ Visit Overview

Study commencement must not occur until Sponsor Green Light process has been completed

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SIV Pharmacy Report Completed By:

Monitor:
Telephone
e-mail:
Signature:
Date:

Completed Responses Approved by Pharmacy:

PI Name:
PI Signature:
Date:

Completed Pharmacy SIV Report Approved By:

Monitor:
Signature:
Date:

