Sponsor Number:	
Study Title:	
Chief Investigator:	
EudraCT Number:	
IRAS Number:	

Pharmacy Site Initiation Visit & Actions Report

1. Site Information

Site Number:	
Site Name:	
Principal Investigator:	
Date of Site Initiation Visit:	
Conducted by:	
Initiation Visit Method:	Onsite ☐ Remote ☐

2. Personnel in Attendance

Name	Title

3. Trial Overview

Items discussed/verified	Comment
Study IMP/s	

4. Training Log

Items Discussed/verified	Yes	No	Comment
Signature Log	☐	☐	Started on DD/MM/YYYY signed by:

5. Contact Details

Items Discussed/verified	Yes	No	Comment
Contact Details	☐	☐	Contact details are present for: XXXXXXXXXXXX vx.x DD/MM/YYYY

6. Trial Synopsis

Items Discussed/verified	Yes	No	Comment
Study Synopsis	☐	☐	vx.x DD/MM/YYYY; Checked and Approved by PERSON DD/MM/YYYY
Document version control history	☐	☐	

Sponsor Number:	
Study Title:	
Chief Investigator:	
EudraCT Number:	
IRAS Number:	

7. Dispensing Procedure

Items Discussed/verified	Yes	No	Comment
Dispensing procedure	☐	☐	vx.x DD/MM/YYYY; Checked and Approved by PERSON DD/MM/YYYY
Pre-printed labels	☐	☐	vx.x DD/MM/YYYY

8. Drug Accountability Procedure

Items Discussed/verified	Yes	No	Comment
Inventory Logs per drug/dose	☐	☐	vx.x DD/MM/YYYY; Checked and Approved by PERSON DD/MM/YYYY: ○ Opening balance recorded DD/MM/YYYY = XX bottles, batch number XXXX, expiry DD/MM/YYYY
Patient Specific *NB that a pharmacy may be using separate individual logs or may be using a combined log*	☐	☐	vx.x DD/MM/YYYY; Checked and Approved by PERSON DD/MM/YYYY
Masters	☐ ☐	☐ ☐	Inventory log templates vx.x DD/MM/YYYY; Checked and Approved by PERSON DD/MM/YYYY. Subject accountability log template vx.x DD/MM/YYYY; Checked and Approved by PERSON DD/MM/YYYY.

9. Prescriptions

Items Discussed/verified	Yes	No	Comment
Master	☐	☐	Prescription template vx.x completed; Checked and Approved by PERSON DD/MM/YYYY.

10. Order and Receipt Procedure

Items Discussed/verified	Yes	No	Comment
Procedure	☐	☐	Orders & Receipts procedure vx.x DD/MM/YYYY; Checked and Approved by PERSON DD/MM/YYYY.
Order	☐	☐	
Receipt	☐	☐	
C of A/QP Release Certificates	☐	☐	
Re-labelling	☐	☐	

11. Returns and Destruction Procedure

Sponsor Number:	
Study Title:	
Chief Investigator:	
EudraCT Number:	
IRAS Number:	

Items Discussed/verified	Yes	No	Comment
Procedure	☐	☐	Returns & destruction vx.x DD/MM/YYYY; Checked and Approved by PERSON DD/MM/YYYY.
Documentation	☐	☐	Evidence (email) of Sponsor authorisation to destroy stock to be retained.

12. Unblinding and Code Break Procedure

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

13. Pharmacy Personnel

Items Discussed/verified	Yes	No	Comment
CVs and GCP Certificates *NB. For UoL Sponsored trials it is acceptable for only the key or lead member of the Pharmacy CT team to be listed on the trial delegation of authority and signature log stored in the TMF as the Pharmacy representative. All other members of the Pharmacy team working on the trial are expected to the listed on the Pharmacy signature and training log stored in the Pharmacy Site File.*	☐	☐	
Trial Specific Training Documentation	☐	☐	

14. Temperature Monitoring

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

15. Correspondence

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

16. Regulatory Documentation

Sponsor Number:	
Study Title:	
Chief Investigator:	
EudraCT Number:	
IRAS Number:	

Items Discussed/verified	Yes	No	Comment
Documentation	☐	☐	
Original Approvals	☐	☐	
Completed Pharmacy Risk Assessment	☐	☐	
Remote Storage Risk Assessment Documentation	☐	☐	
Completed Clinical Trials Review Form	☐	☐	
Completed Folder Audit Forms	☐	☐	

17. Finance

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

18. Protocol

Items discussed/verified	Yes	No	Comment
Protocol	☐ ☐	☐ ☐	
Pharmacy Manual	☐	☐	

19. Investigator Brochure/SPCs

Items discussed/verified	Yes	No	Comment
Investigator Brochure	☐	☐	
SmPCs	☐	☐	

20. Superseded Pharmacy Documents

Items discussed/verified	Yes	No	Comment
Superseded Documents	☐	☐	

Additional Comments/ Visit Overview

The trial must not start until Sponsor Green Light has been issued

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Pharmacy SIV and Actions Report

Site Number:	
Site Name:	
Sponsor Reference Number:	
Short Study Title:	

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

The trial must not start until Sponsor Green Light has been issued

No.	Outstanding Issue	Action required	Action Taken	Signature & Date	Sponsor review/sign-off & date

Pharmacy Initiation Visit and Report Completed by:	Responses Completed by:	Principal Investigator/Pharmacy Lead Sign-off:
Name:	Name:	Name:
Role:	Role:	Role:
Email:	Email:	Email:
Signature:	Signature:	Signature:
Date:	Date:	Date:

Pharmacy Initiation Visit and Report Closed by:
Name:
Role:
Email:

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Pharmacy SIV and Actions Report

Site Number:	
Site Name:	
Sponsor Reference Number:	
Short Study Title:	

Signature:
Date: