

Stem Cell Lab Visit Report – Pharmacy Monitoring Form

Protocol Title:	
Trust Reference Number:	
Eudract Number	
Principal Investigator:	
Date of visit:	
Date of Report Issued:	
Date Response Due Back:	

Study Specific Details

Items discussed/verified	Comment
Study ATIMP	

Training Log

Items Discussed/verified	Yes	No	N/A	Comment
Site Initiation Visit Signature log completed in Lab Site File	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comment/Findings:				

Contact Details

Items Discussed/verified	Yes	No	N/A	Comment
Appropriate Contact details recorded	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings:				

1. Synopsis

Items Discussed/verified	Yes	No	N/A	Comment
Current study protocol version in Lab Site File	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Document version control history	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings:				

2. Issuing

Items Discussed/verified	Yes	No	N/A	Comment
ATIMP issue procedure recorded and present in the Lab Site File	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Stem Cell Proforma in the Lab Site File	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Sample Product and Batch labels in the Lab Site File	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings:				

3. ATIMP Accountability

Items Discussed/verified	Yes	No	N/A	Comment
Inventory logs completed and reconciled with QP certificates				
Patient specific logs completed fully and reconciled with QP certificates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Master copies present in the Lab Site File	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings:				

4. Prescriptions/Worksheets

Items Discussed/verified	Yes	No	N/A	Comment
Prescriptions screened and completed correctly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Issue Form, Prescriptions and Accountability logs reconciled	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Approved Prescription Template in the Lab Site File	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings:				

5. Order and Receipt

Items Discussed/verified	Yes	No	N/A	Comment
Proforma request form present if applicable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Master Proforma request form present	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Request for ATIMP form present if applicable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Master request for ATIMP form present	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Certificate of authorisation/QP release certificates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Re-labelling/Batch Labels	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings:				

6. Returns/Destruction

Items Discussed/verified	Yes	No	N/A	Comment
Procedure recorded	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Documentation of return/destruction recorded	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings:				

7. Out of hours support – if applicable

Items Discussed/verified	Yes	No	N/A	Comment
ATIMPs quarantined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Quarantine paperwork complete	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
File note completed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings:				

8. Lab Personnel

Items Discussed/verified	Yes	No	N/A	Comment
CVs and GCP certificates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Storage, handling, receipt, issue, return/destruction training documentation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings:				

9. Temperature Monitoring

Items Discussed/verified	Yes	No	N/A	Comment
Temperature log reviewed for ATIMP Nitrogen Tank				
Temperature monitoring file note if applicable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Temperature deviation information if applicable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Nitrogen Tank for ATIMP location viewed and no changes to agreed location	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Contingency Nitrogen vat on site	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings:				

10. Correspondence

Items Discussed/verified	Yes	No	N/A	Comment
Monitoring log and reports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Correspondence	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings:				

11. Regulatory Documentation

Items Discussed/verified	Yes	No	N/A	Comment
Amendment documentation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

SOP adapted from Pharmacy Visit Report Appendix 7 to S-1007 UHL Site Management (Monitoring) of research for University Hospitals of Leicester NHS Trust when acting as Sponsor Version 8 January 2018

Original approvals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Completed joint pathology/pharmacy risk assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lab assessment documentation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Completed clinical trials review form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Completed folder audit forms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings:				

13. Protocol

Items discussed/verified	Yes	No	N/A	Comment
Protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pharmacy manual	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings:				

14. Investigator Brochure/Lab Manuals

Items discussed/verified	Yes	No	N/A	Comment
Investigator Brochure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lab Manuals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings:				

15. Superseded Lab Documents

Items discussed/verified	Yes	No	N/A	Comment
Superseded documents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings:				

Additional Comments/ Visit Overview

Stem Cell Lab Monitoring Visit Response Document
Clinical Trial Name and Dog Number: _____

Monitoring visit Date:

Monitoring visit report date:

Date response required:

Outstanding Issue	Action required	Action Taken	Clinical Trials Pharmacist

Pharmacy Monitoring Report Completed By: _____

Pharmacy Monitoring Report Response Completed By: _____

Pharmacist :
Telephone:
e-mail:
Signature:
Date:

Completed Responses Approved by PI:

PI Name:
PI Signature:
Date:

Completed Monitoring Report Approved by:

Lead Pharmacist :
Signature:
Date Monitoring Report Closed: