

---

## Stem Cell Lab Visit Report

---

Organisation: The Christie

Document version number: V1.0

Date written: Aug -2018

### End user rights:

This document is shared with permission for re-use to distribute, remix, adapt, and build upon the material in any medium or format for non-commercial purposes only, so long as the attributions listed below are given.

Attributions: Name of Organisation; [others as required by Organisation to be listed here]

This document is made available under a Creative Commons Attribution-NonCommercial 4.0 International License as described here:

<https://creativecommons.org/licenses/by-nc/4.0/>

The information, materials and any opinions contained in this document are provided for general information and educational purposes only, are not intended to constitute legal, medical or other professional advice and should not be relied on or treated as a substitute for specific advice relevant to particular circumstances. Although we make all reasonable efforts to ensure the information is up to date, we make no representations, warranties or guarantees in that regard. In no event shall the creator(s) be liable for any direct, indirect, special, consequential or other claims, losses or damages that are related to the use or reliance whatsoever in the content of

Funded by

Coordinated by

the document or any part thereof, except to the extent that such liability cannot be excluded by law. We do not seek to exclude or limit in any way our liability to the user for personal injury or death caused as a result of our negligence or seek to exclude or limit our liability for fraud or fraudulent misrepresentation by us.

We reserve the right to make changes and improvements to any information contained within this document, at any time and without notice. Where this document contains hyperlinks to other websites operated by parties not connected to us, such hyperlinks are provided for your reference only. We do not control such websites and are not responsible for their contents. The inclusion of hyperlinks from this document or the website to such websites does not imply any endorsement of the material on such websites or any association with their operators. We accept no responsibility of any nature whatsoever for linked web sites or any information contained in them.

Funded by

Coordinated by

**Stem Cell Lab Visit Report – Pharmacy Quarterly Visit Monitoring Form**

Date of the last annual audit:	
Date of the last Pharmacy quarterly visit:	
Date of visit:	
Quarter period:	(MM/YYYY-MM/YYYY)
Date of Report Issued:	
Date Response Due Back:	

**Details of ATIMPs and ATMPs stored**

ATIMP or ATMPs	Comment
Trials open and related ATIMPs currently stored in the stem cell labs	1. 2. 3. 4.
ATMPs approved and stored for clinical services	1. 2. 3.

**Training Log**

Items Discussed/verified	Yes	No	N/A	Comment
New staff appointed and trained in handling ATMP and ATIMPs named above	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Comment/Findings:</b>				

**Temperature Records**

Items Discussed/verified	Yes	No	N/A	Comment
Temperature excursions during this report quarter period	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Corrective actions from previous reports relating to temperature excursions implemented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Comments/Findings:</b>				

**Product Defects/Non-conformance**

Items Discussed/verified	Yes	No	N/A	Comment
Non-conformance reported for this quarter period	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Corrective actions from previous reports relating to product defects/non-conformance implemented				

*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*

Stem Cell Lab Visit Report – Pharmacy Quarterly Visit Monitoring Form

Author: Nisa Khan Reviewed/Approved by: Diane Sweeny  
August 2018 Version 1.0

Product defects/recalls in this quarter period	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Comments/Findings:</b>				

**Waste Management**

Items Discussed/verified	Yes	No	N/A	Comment
No. of expired/unused ATMPS in this quarter period	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Deviations identified from waste management SOP	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Comments/Findings:</b>				

**Out of hours support – if applicable**

Items Discussed/verified	Yes	No	N/A	Comment
ATIMPs or ATMPs quarantined in this quarter period out of hours?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Quarantine paperwork complete for this quarter period?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Corrective actions from previous reports relating to our of hours implemented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Comments/Findings:</b>				

**Miscellaneous**

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

**Additional Comments/ Visit Overview**

**Stem Cell Lab Monitoring Visit – Pharmacy Quarterly Visit Response Document**

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: \_\_\_\_\_

*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*

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

**Completed Responses Reviewed by HTA DI:**

PI Name:
PI Signature:
Date:

**Completed Monitoring Report Approved by:**

Lead Pharmacist :
Signature:
Date Monitoring Report Closed: