

# Example checklist for transfer of shippers to clinical areas and their return to the sending laboratory

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## Example checklist for transfer of shippers to clinical areas and their return to the sending laboratory

**30 Nov 2020**

This document sets out an example generic checklist for transfer of shippers containing Advanced Therapy Medicinal Products (ATMPs) to clinical areas, and their return to the sending laboratory. It may require adaptation to accommodate local procedures or product-specific requirements. The checklist should be adjusted to reflect whether the ATMP is received direct from the manufacturer or via an on-site or external Stem Cell Laboratory. Institutional readiness checklists produced by the Pan-UK Pharmacy ATMP Working Group for relevant cellular ATMP type should also be considered. (Available from <https://www.sps.nhs.uk/>).

## TRANSFER OF DRY SHIPPER TO CLINICAL AREA CHECKLIST

### Planned ATMP administration

Product Name		
Storage requirements for particular product <sup>1</sup>	(e.g. in vapour phase of liquid nitrogen $\leq -150^{\circ}\text{C}$ )	
Patient name		
Patient date of birth		
Patient hospital number/ NHS number		
Requesting clinical area		
Date & time product required to reach clinical area (see infusion request form doc no.XXX)		
Date & time of product receipt		
	<b>1<sup>st</sup> person</b>	<b>Back up</b>
Stem cell staff available for dispensing checks		
Second check staff available for dispensing checks (may occur in clinical area or stem cell lab, may be stem cell lab staff with pharmacy oversight or pharmacy staff depending on set up)		

NB for dispensing checklist see separate checklist document

<sup>1</sup> For storage requirements check [www.medicines.org.uk](http://www.medicines.org.uk) or trial documentation

On receipt of ATMP at storage facility (if applicable)

Checking step/data	Yes/No/NA/Date	Checker initials	Date & time
Receipt checklist completed & sent to pharmacy	Yes / No / N/A		

Day before administration

Checking step/data	Yes/No/N/A	Checker Initials	Date & time
Shipper prepared (Primary and back up shipper)	Yes / No		
Courier arranged if required	Yes/N/A		

Day of administration

Checking step/data	Yes/No	Checker Initials	Date & time
Shipper check – shipper weight & no liquid nitrogen present (if not completely dry pour out excess and leave to equilibrate as per SOP XXX)	Yes / No		
Shipper check – temperature monitor active, settings correct and temperature in range, shipper visual check complete (no dents etc.)	Yes / No		
Shipper validated minimum static hold time $\leq -150^{\circ}\text{C}$ (e.g. 72 hours)	.....hours		

Checking step/data	Yes/No	Checker initials	Date & time
Hold time sufficient until administration	Y/N		
Dispensing checklist completed including check of temp during storage (evidence provided), certificate of release & product integrity check	Y/ N		
Shipper label complete including contact number if issue with temp/storage time etc	Y/N		
Shipper sealed & tamper evident	Y/N		
Paperwork complete	Y/N		
Issue product on stem cell laboratory electronic system and update storage documents/system	Y/N		
Location to be taken/person to collect			

Handover of shipper and paperwork	Name	Signature	Date	Time
Stem cell lab representative Healthcare professional or courier				

## RETURN OF DRY SHIPPER TO CLINICAL AREA CHECKLIST

Checking step\data	Yes/No/N/A	Checker Initials	Date & time
Administration paperwork completed and returned/ Filed in medical notes	Yes / No / NA		
Shipper returned to sending laboratory along with this paperwork	Yes / No		
On receipt at sending laboratory, download temperature logger data, check for excursions and send log to clinical area/pharmacist	Yes / No		
Shipper decontaminated as required	Yes / No		