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Addressing issues for ATMP logistics

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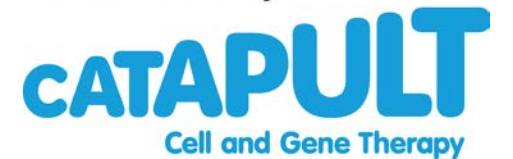
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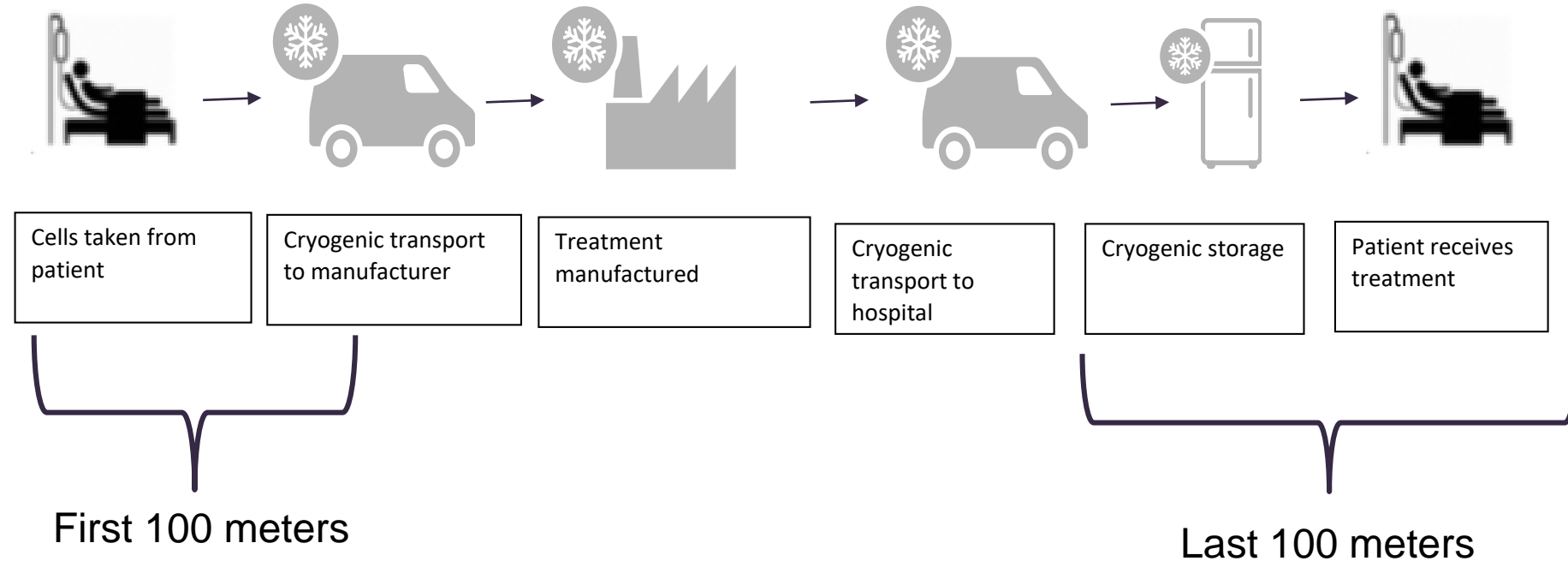
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Background



What we have done

Workshop with multiple stakeholders – confirmed guidance needed on first/last 100m

Test deliveries across multiple sites in MW-ATTC and lessons learned

Gap analysis carried out by NA-ATTC

Multiple follow up interactions across NHS

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Issues faced within hospitals

- Most hospitals have grown organically over time, no two hospitals are alike (challenging to give standard advice)
- Cell/gene therapies are still new to most hospitals – lack of experience or established teams
- Cell therapy pathway is long and complex, especially so for autologous therapies
- Depending on the treatment there are multiple treatment pathways within a hospital
- Large team involved in safe delivery, multiple disciplines involved
- Pharmacy needs to have oversight of ATMP at receipt from courier to delivery to patient
- Infrastructure not in place for storage on site everywhere meaning ATMPs may need to be stored offsite (e.g. NHS-BT). Wi-Fi blackspots etc...space and flexibility of pharmacy facilities
- Stem cell labs required for cryogenic (-150°C) storage not usually involved in storing medicines inexperienced with the regulatory framework surrounding medicines

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Infrastructure

Common issues	Potential solutions
No pharmacy storage for ATMPs	<p>Pharmacy working group (PWG) is developing standard guidance for working with external groups to store ATMPs</p> <p>NHS-BT providing off site storage for some hospitals</p> <p>Footprint for shipping units development of agreements</p>
Maintaining temperature during final transit to administration	<p>Use dry ice or vapour phase cryogenic container to transport ATMP within hospital.</p> <p>Agreement on responsibilities for equipment</p>
Institutions develop a system that is only suitable for a small number of treatments	<p>Institutions need to consider the viability of their internal receipt, storage and dispensing routes for in ever increasing number of treatments</p>
Wi-Fi blackspots	<p>Test runs to identify issues and hospitals</p>
Storage requirements prior to shipping offsite	<p>Commonality is being identified by SAMPLE project</p>

Governance

Common issues	Potential solutions
<p>Pharmacy need oversight of ATMP storage when not held in pharmacy</p>	<p>PWG are developing standard guidance for working with external groups to store ATMPs</p>
<p>Lack of governance in place for ATMPs</p>	<p>ATTCs sharing best practice on governance structure with other hospitals Institutional readiness development across ATTCs GM and safety committees that are comfortable with procedures and products</p>

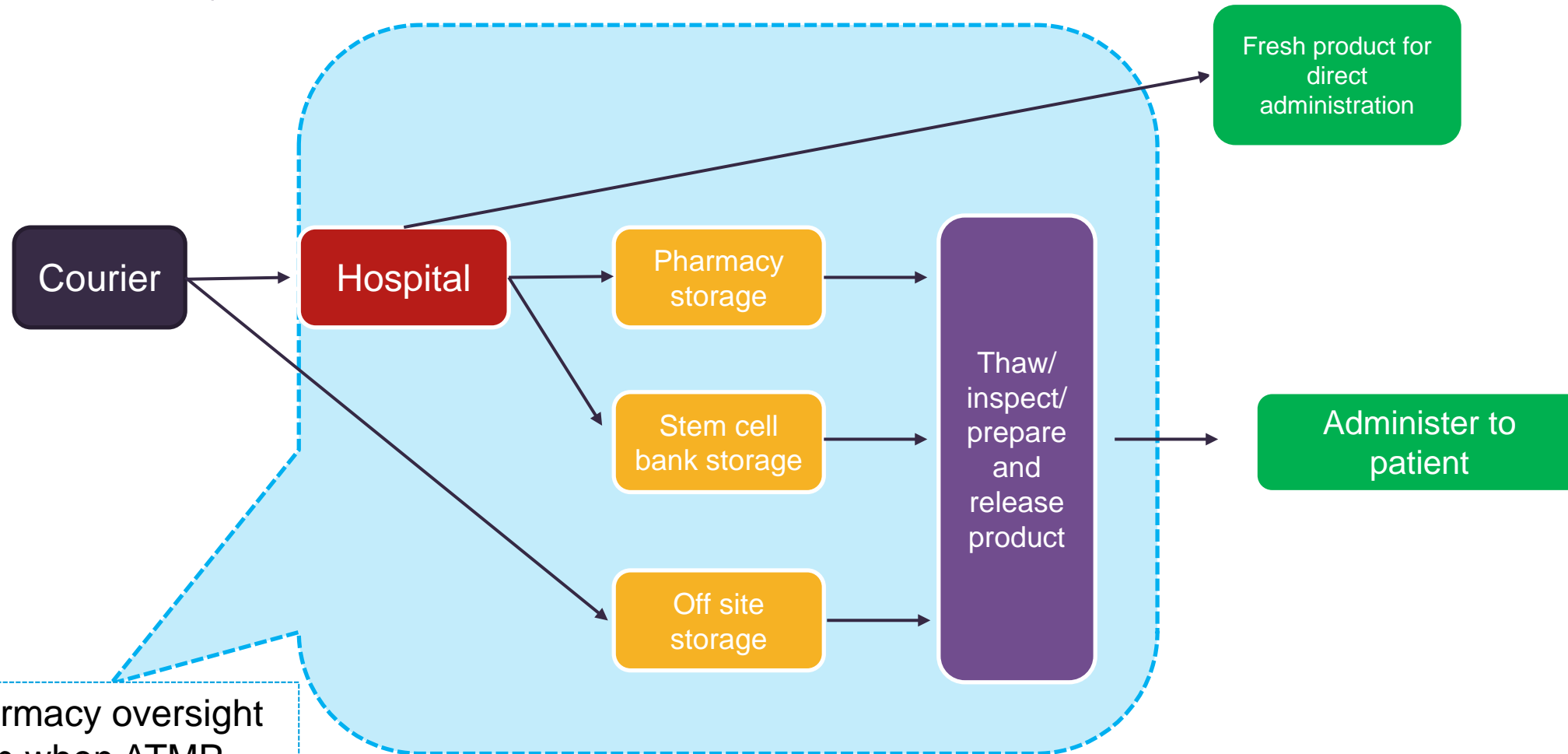
Team

Common issues	Potential solutions
Provision of oversight for pharmacy without holding medicines in their facility	Pharmacy need to develop service level agreement or technical agreement with whichever party is storing treatment.
Stem cell labs inexperienced with the regulatory framework surrounding medicines	Pharmacy can educate teams on the requirements, establish governance for advanced therapies. Very clear pharmacy manuals from sponsors / vendors
Pharmacy are unfamiliar with Stem cell labs processes and storage devices along with hazards, limitations and monitoring	Stem cell lab can educate pharmacy on their facilities and procedures
Poor communication leading to an increased risk of lost products or delays in treatment	There is a need for well defined communication channels. Multi-disciplinary team from hospital door to patient established with regular update meetings being held to raise and resolve issues arising develop coordinating teams and roles across departments and disciplines Communication to patient as needed post administration issues starts with prescription
Lack of coordination across interlinked elements of the process	Well defined team and communication channels across the disciplines

Well defined pathways

Common issues	Potential solutions
<p>Lack of clarity of delivery point preventing the courier finding the delivery destination</p>	<p>Clear instructions given to manufacturer and courier companies. Walk through the path with delivery companies from arrival to hand over point can have multiple pharmacies within facilities, (follow yellow lines) couriers commonly have subcontracted drivers, can't assume same driver day to day</p>
<p>Lack of actual name to deliver to due to uncertainty with shift patterns</p>	<p>Deliver to job role or agreed backup team. Have clear contact details and escalation contact points Define delivery times with vendors, clear communication plans</p>

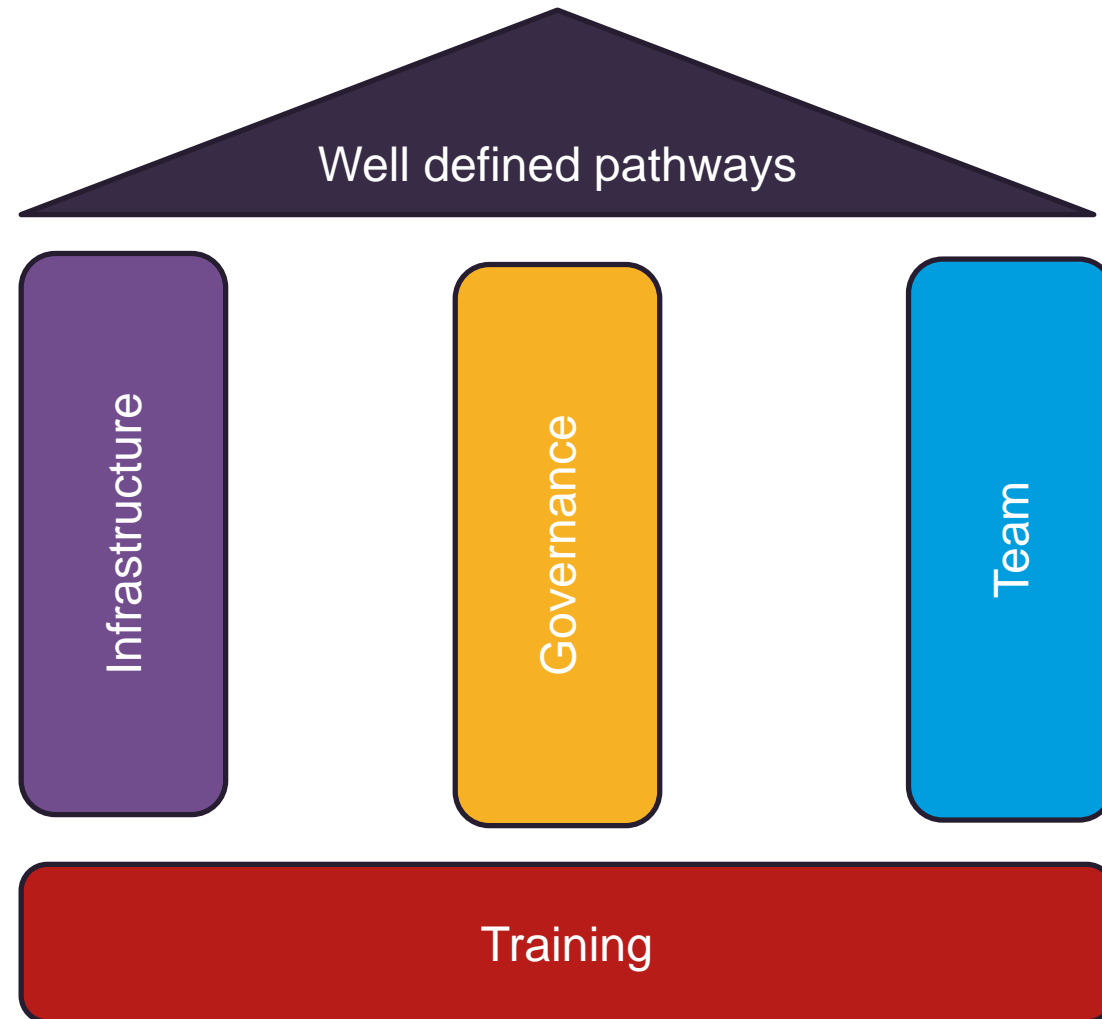
Pathway from courier to patient



Pharmacy oversight even when ATMP not in pharmacy area

Bringing it all together

All elements play a part
in delivering ATMPs to
patients



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Next steps

Produce guidance paper for hospitals to set up or improve their internal logistics

PWG producing guidance for working with stem cell labs and blood services

Describe ATMP coordinator role to help solve communication issues

Sharing of governance procedures across hospitals

Input sought

- What are your pain points, are we covering them based on your experience?
- What examples of good or bad practice have you seen?
- Please share your thoughts (Ian.Hollingsworth@ct.catapult.org.uk)