



**Specialist  
Pharmacy  
Service**



# **Institutional Readiness: Governance & Operational Delivery Considerations**

**Anne Black**

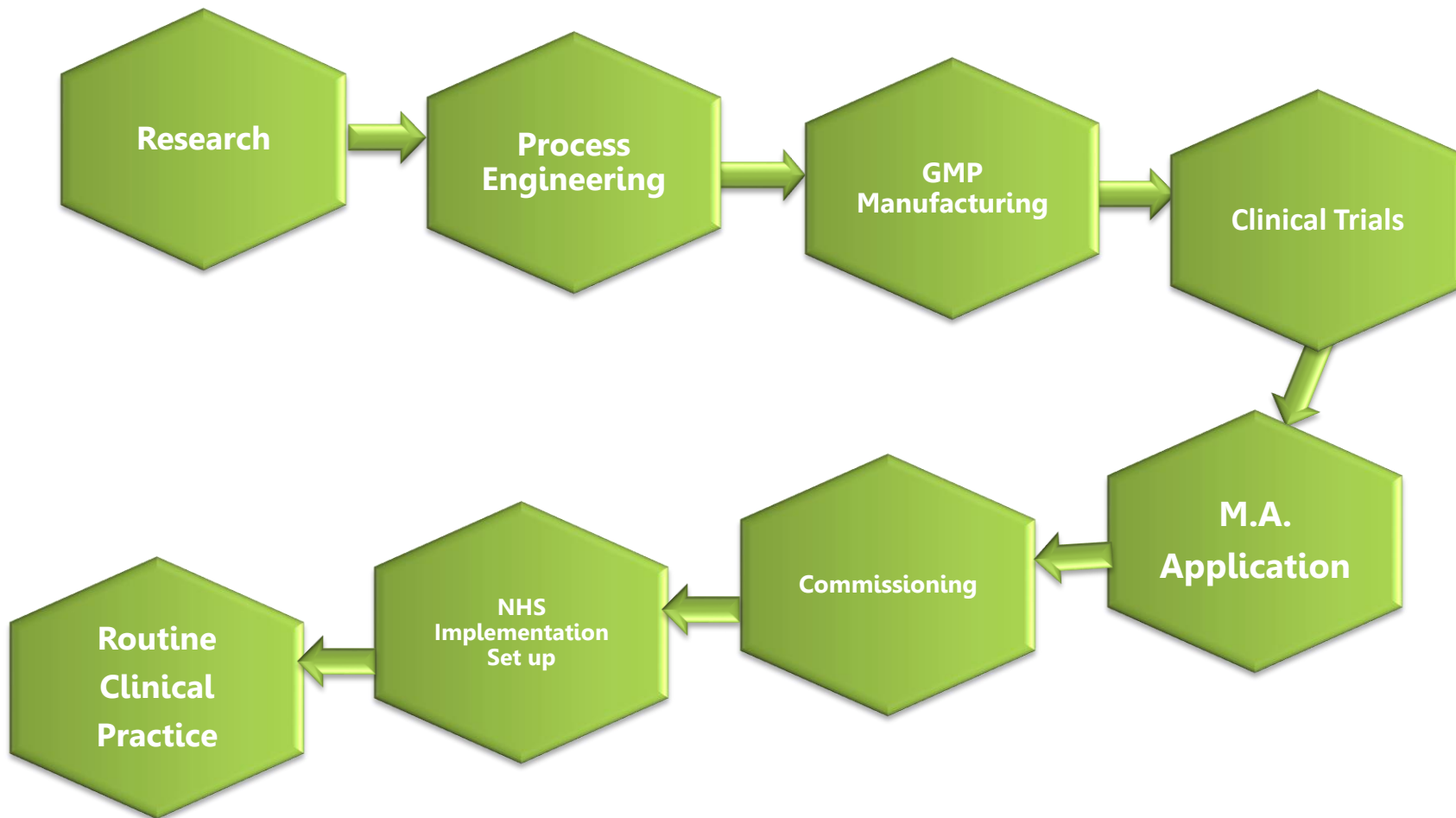
Regional QA Specialist Pharmacist

Pan UK Pharmacy Working Group for ATMPs – Chair

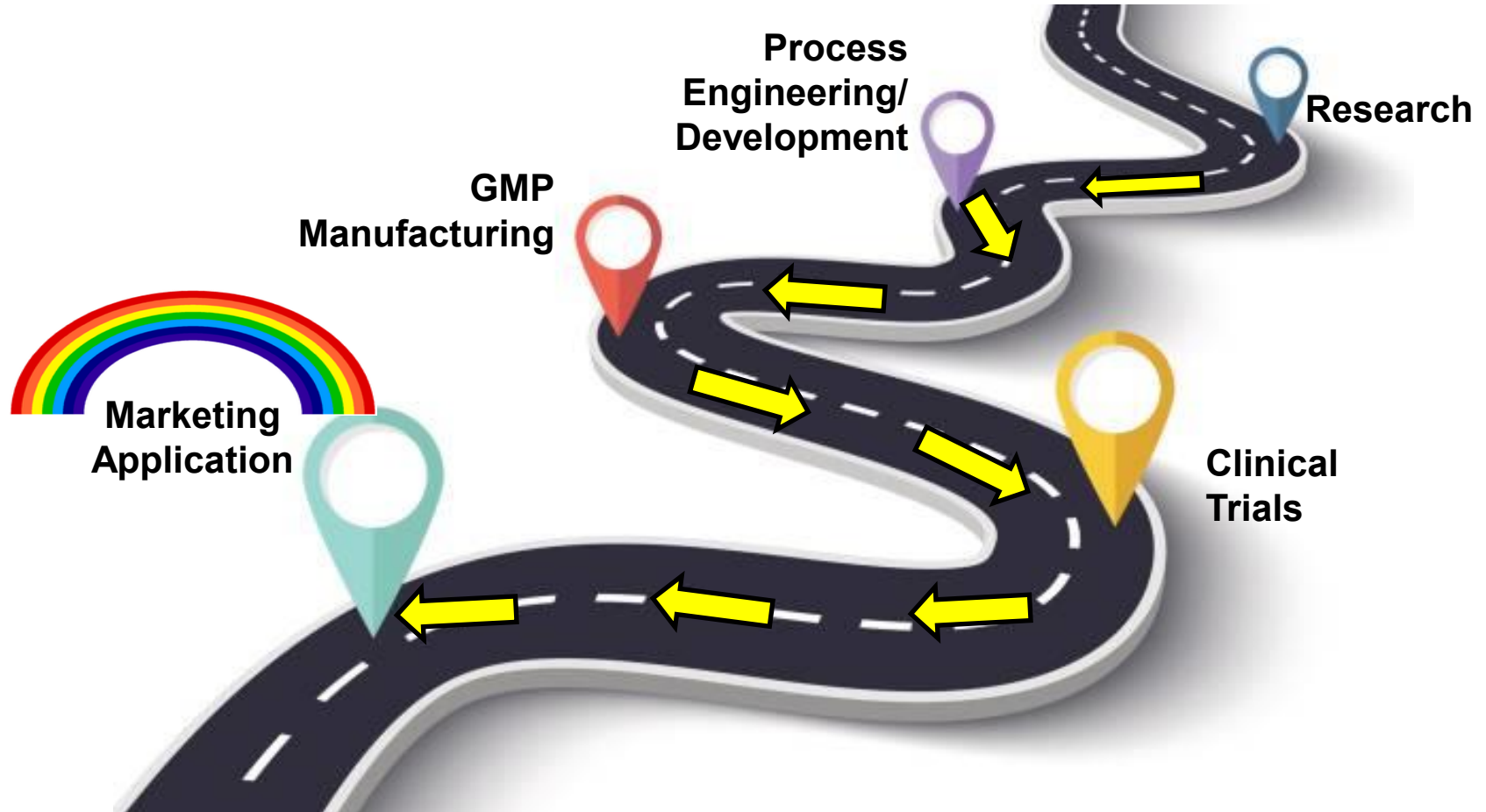


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# ATMP Innovation Pathway



# Developers Journey



**What keeps patients safe?**

**Regulatory Controls: GMP & GCP**

**Clinical trials have risks controlled if key stakeholders are engaged**

# Implementation Journey

NHS  
Implementation  
Set Up

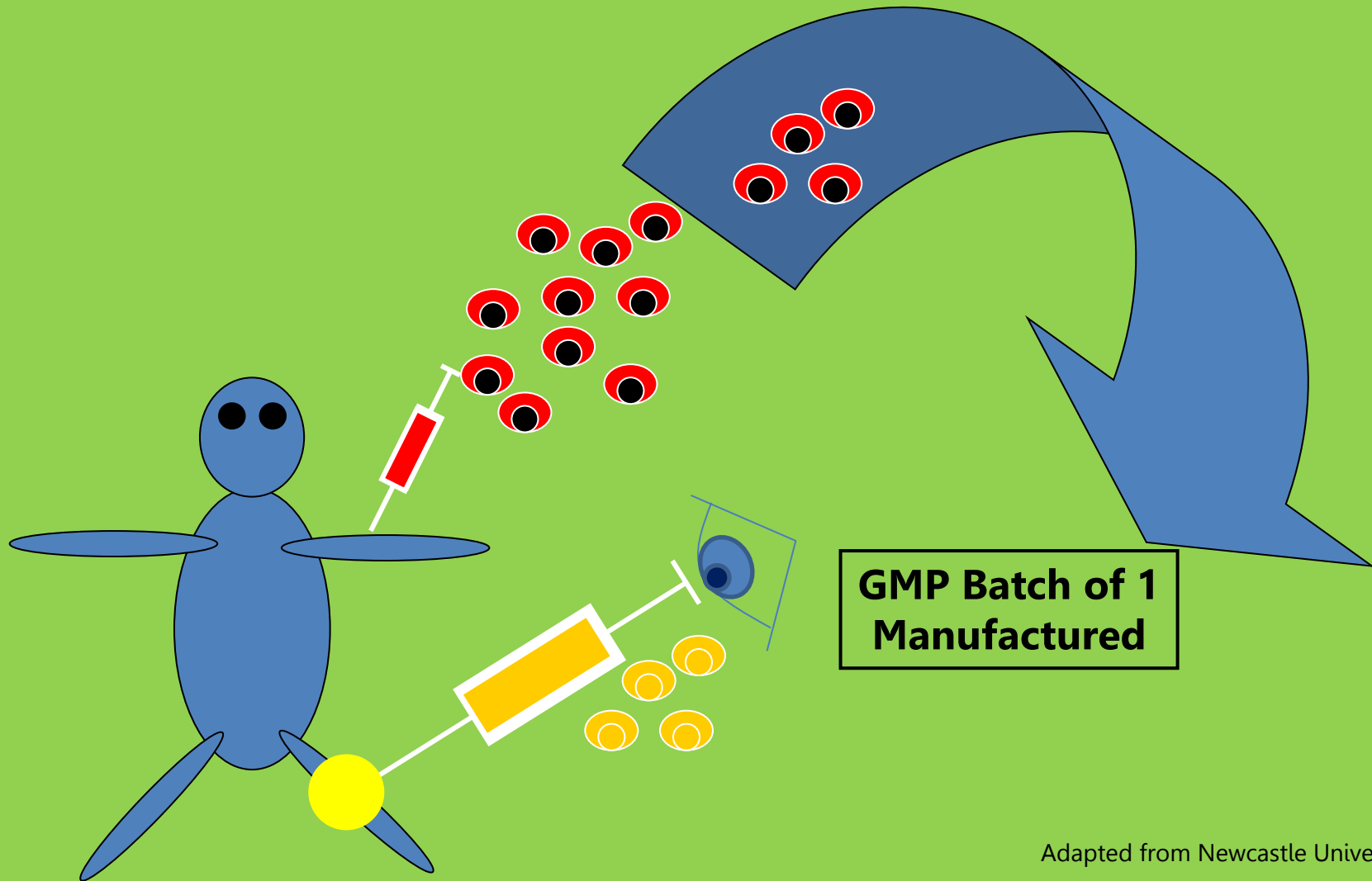
Marketing  
Authorisations

Commissioning  
- NICE  
- NHSE

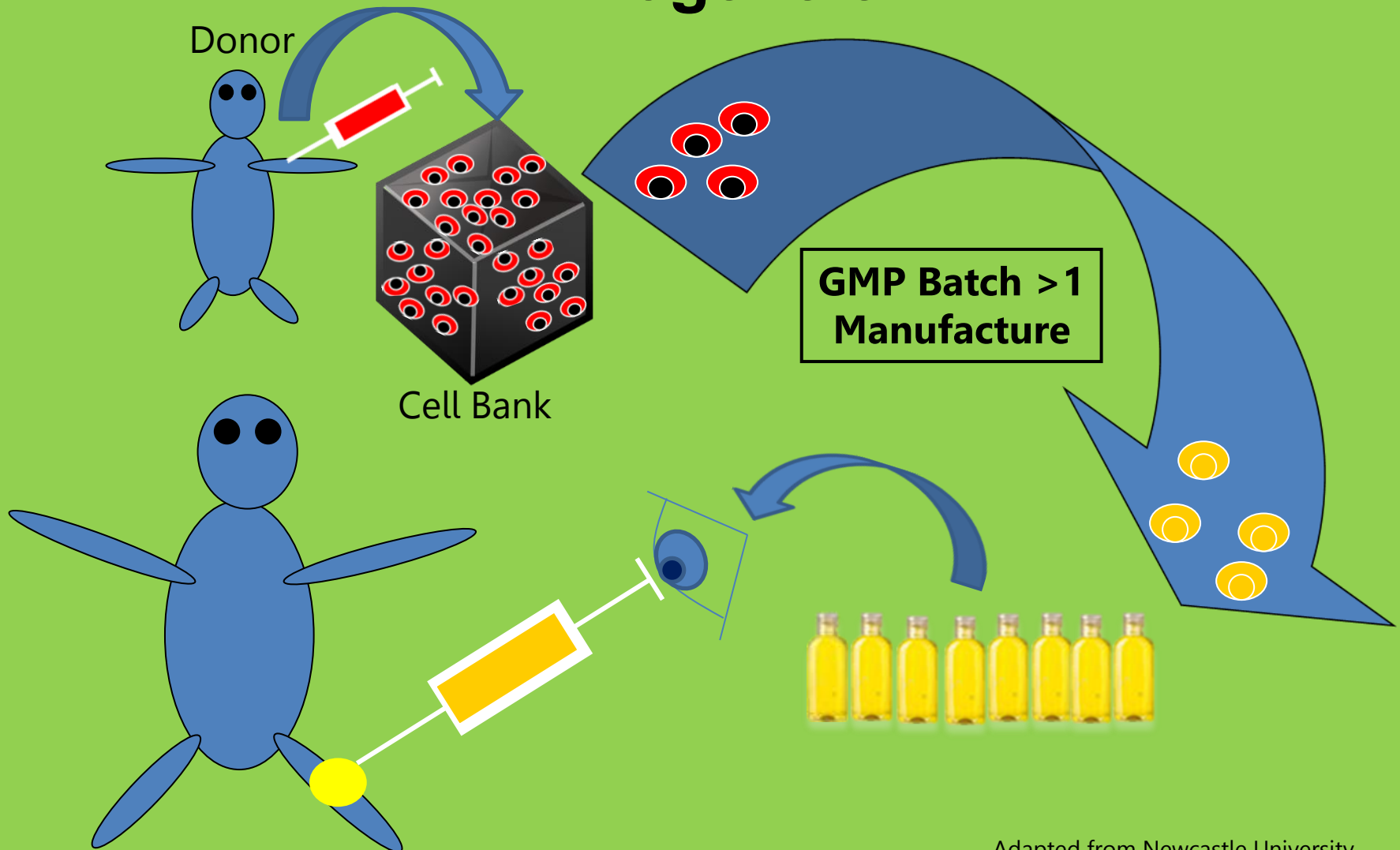
Routine Clinical  
Practice  
- Patient Benefits

**What keeps Patients Safe?**  
**Less Clear – SPC?**  
**Limited experience in NHS**  
**High Risk Medicines – Governance Required**

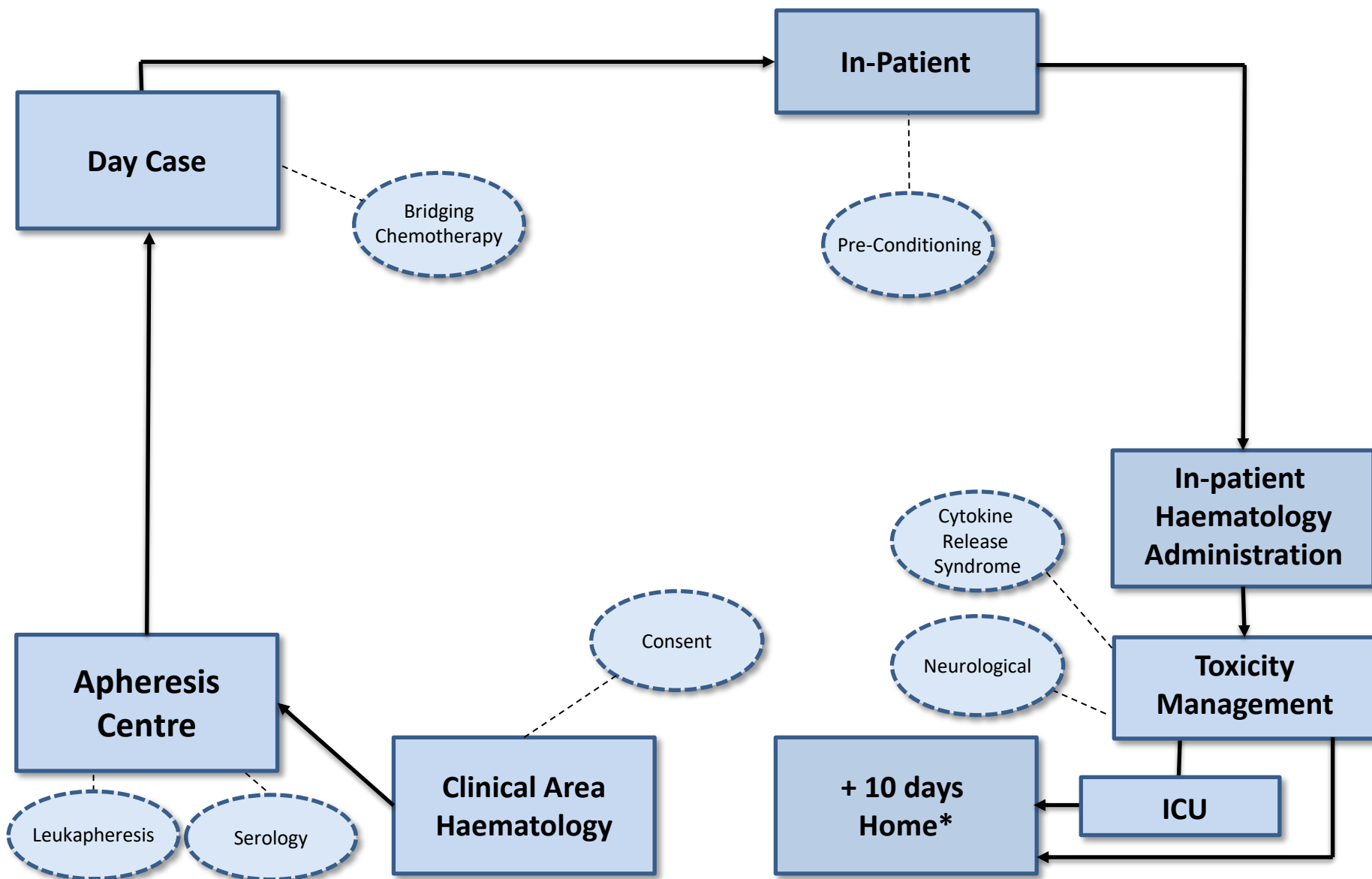
# The Patient Perspective Autologous



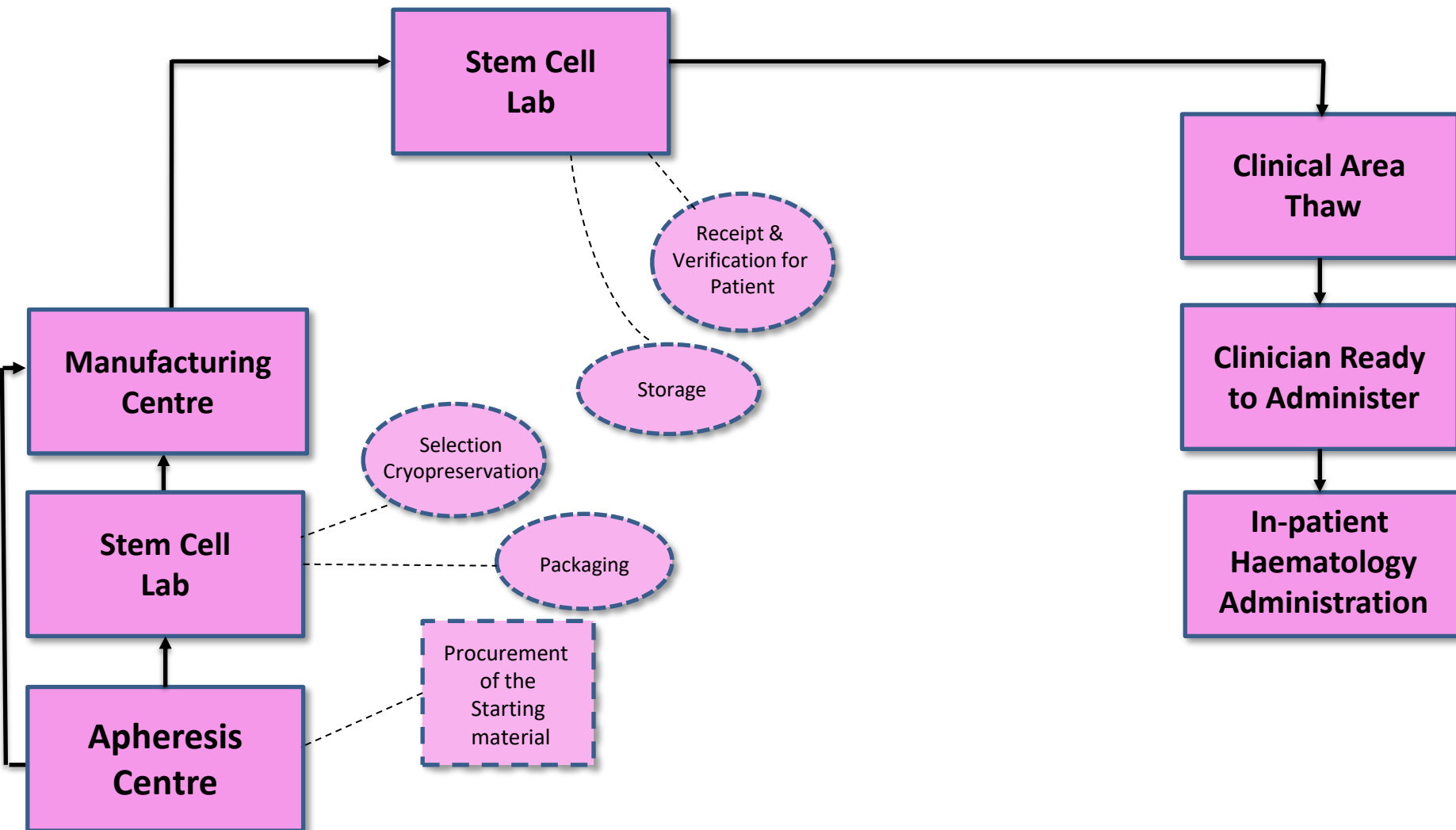
# The Patient Perspective Allogeneic



# CAR-T Patient Journey

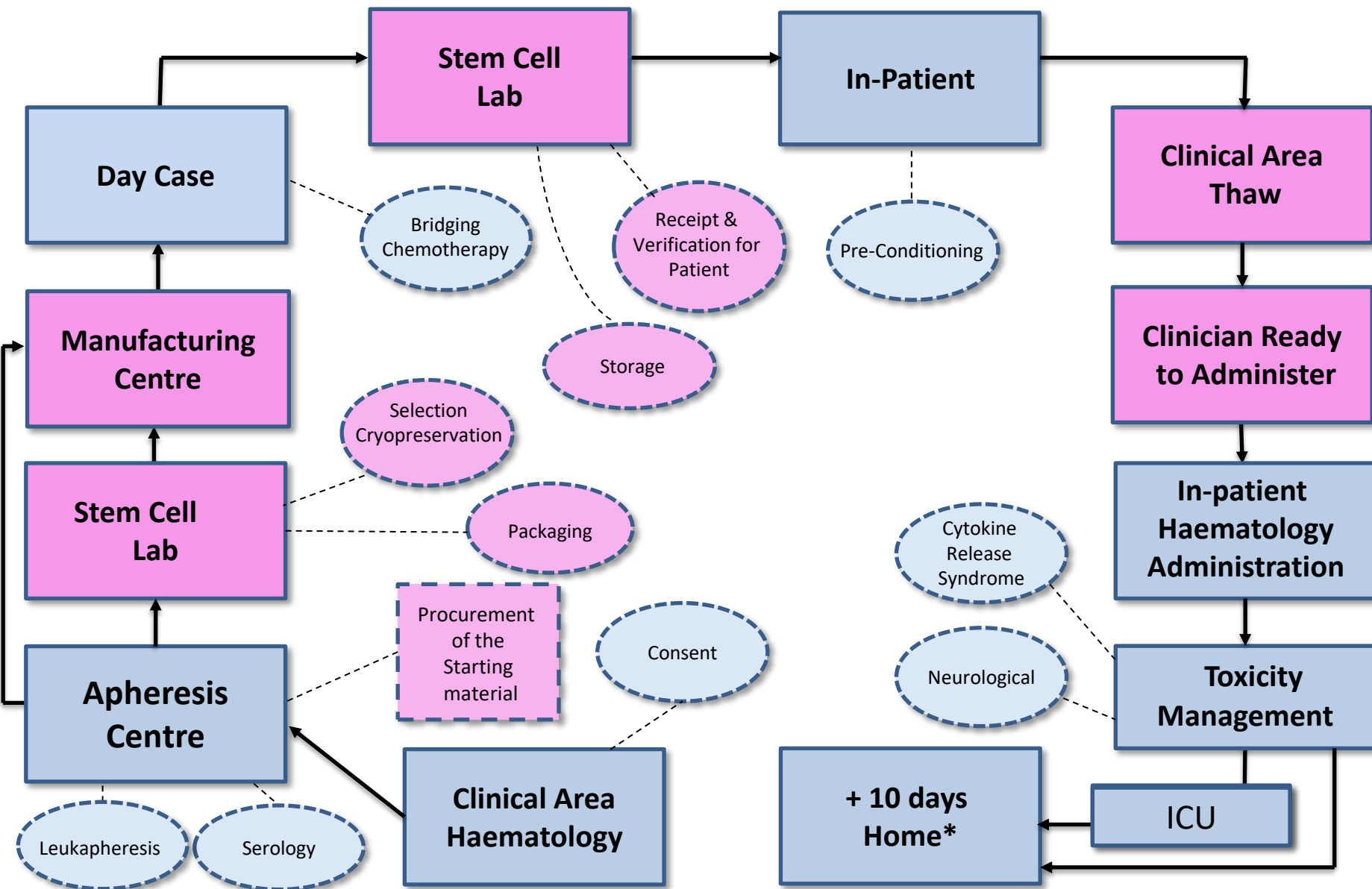


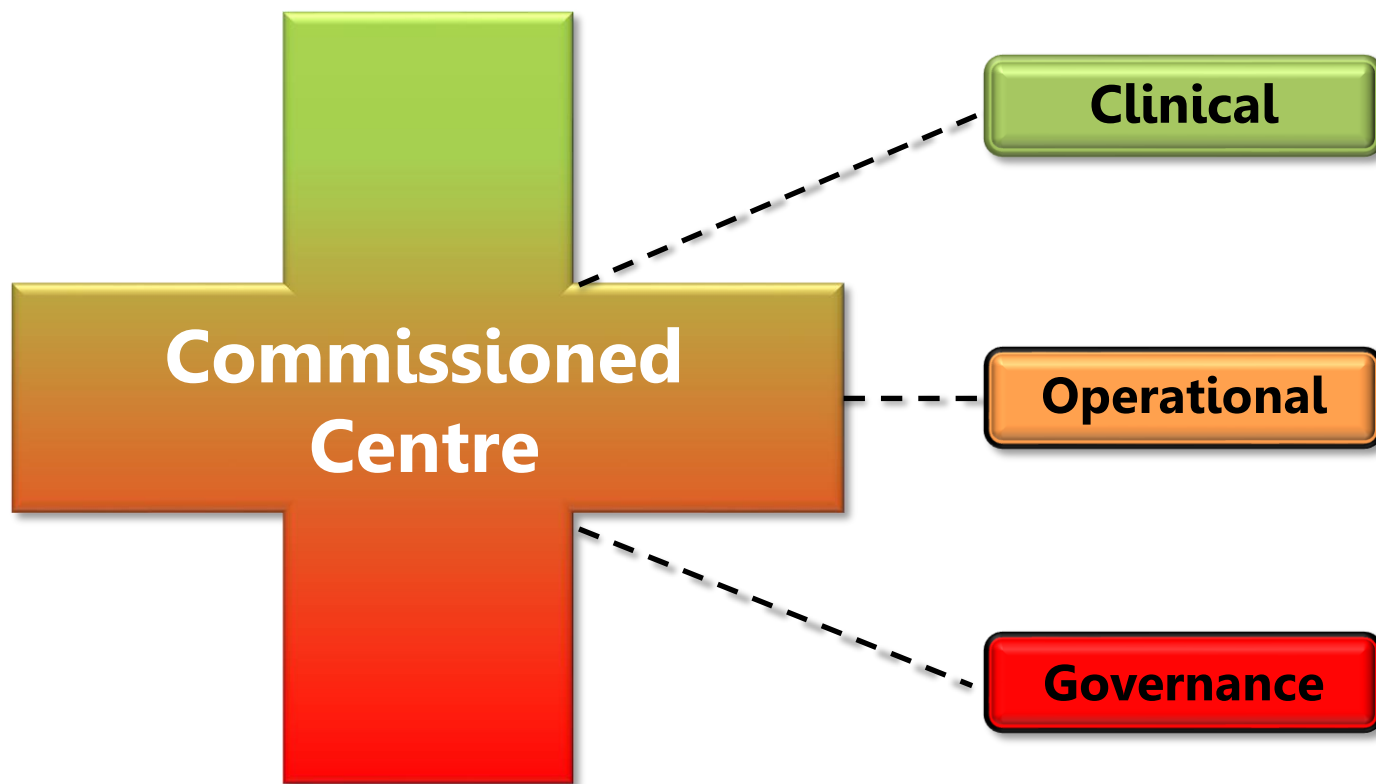
# CAR-T Product Journey

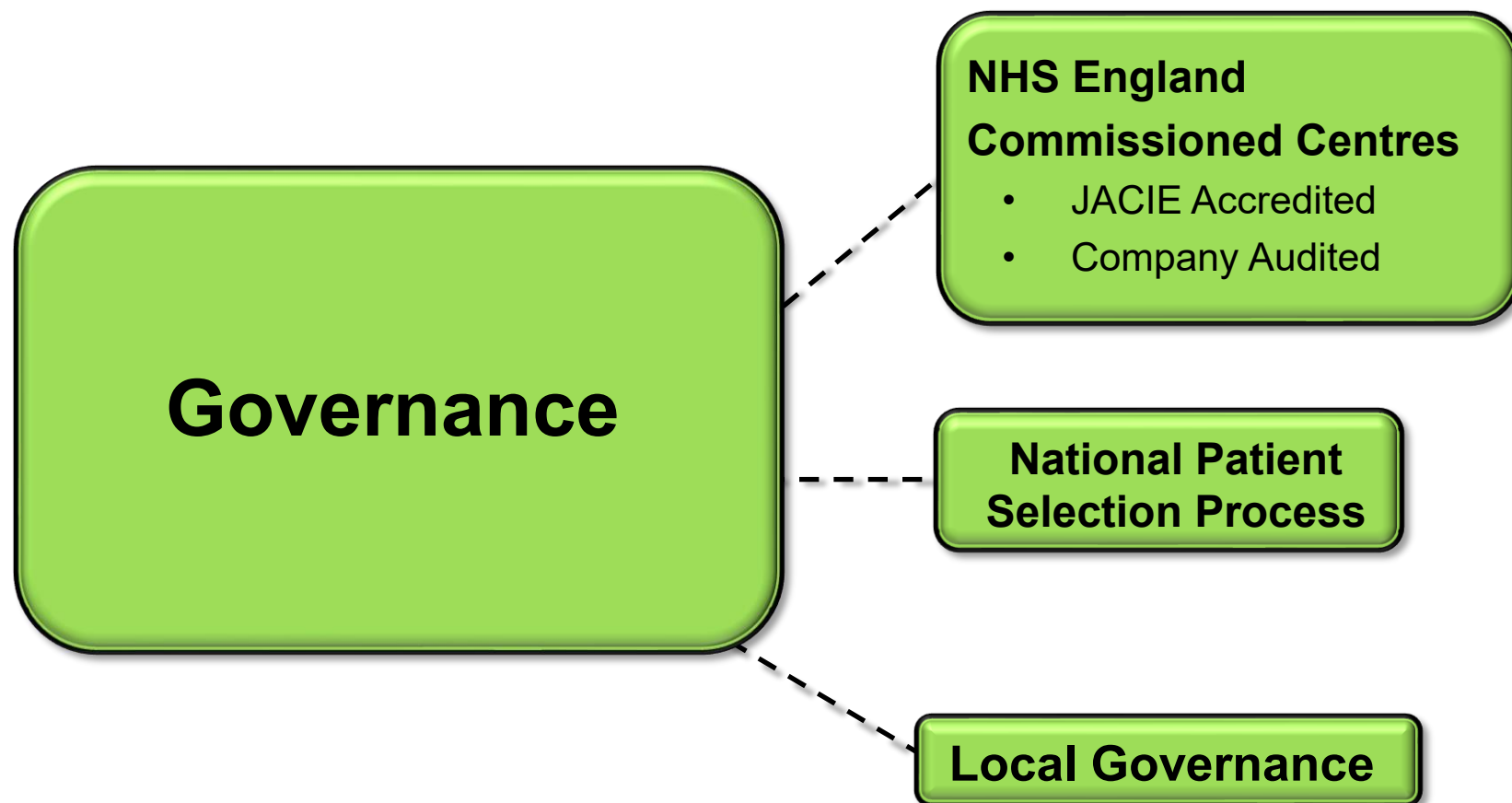




# CAR-T Combined Journey







# Local Governance

## Medicines Management

The Role of Pharmacy in the  
Successful Delivery of  
Advanced Therapy Medicinal Products (ATMPs)  
Information for Chief Pharmacists

Edition 1

February 2017



## Other Aspects

- Communication
- Interfaces
- Primary Care
- Media

# Medicines Management “ATMP Policy”

Licensed Medicines

Clinical Trials

Unlicensed Medicines

# Clinical Trials

## Approvals

- Medicines Management/  
D&T/R&D

Implement via Protocol

# Unlicensed Medicines

Add ATMP to ULM  
Policies

# Licensed ATMPs e.g. CAR-T Therapy

## Financial

- High cost drugs
- Tariff and Reimbursement

## Committees

- Medicines Management
- Drug & Therapeutics
- New Interventional Procedure Committee
- Access to Drugs Process

## Regulatory

- HTA (JACIE) MHRA

Contract Negotiations

# ATMP Medicine Management

## Bespoke Therapy

- Deviations
- Cancellations
- Recalls
- Out of Specifications

## High Cost Drug

- Financial monitoring
- Blueteq

## Novel Medicine

- Pharmacovigilance
  - Yellow card scheme



# Clinical Pharmacy Governance

Patient Verification

Toxicity Management

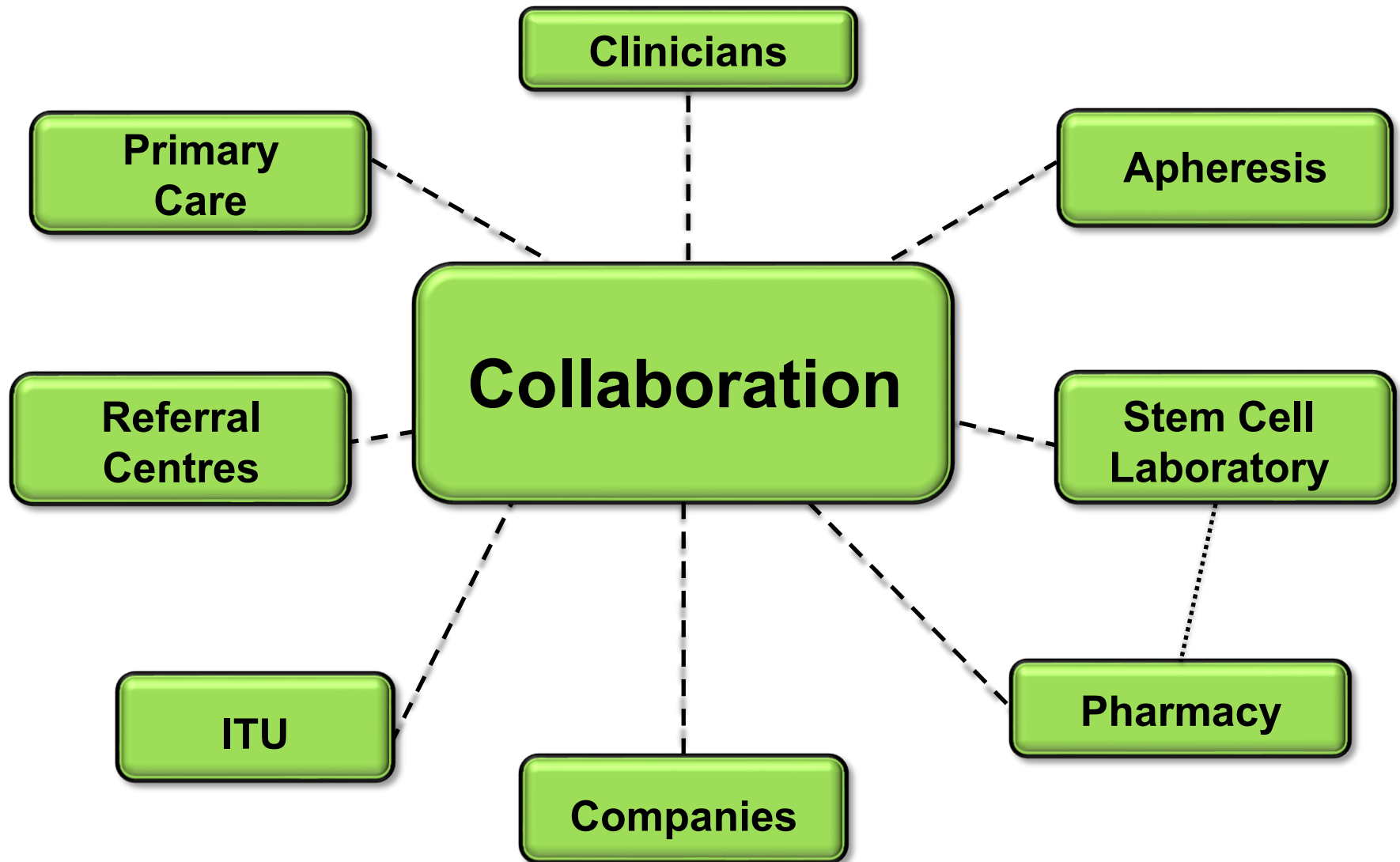
# How to Assure Governance is Appropriate

**Organisational Policies**

**Local Procedures**

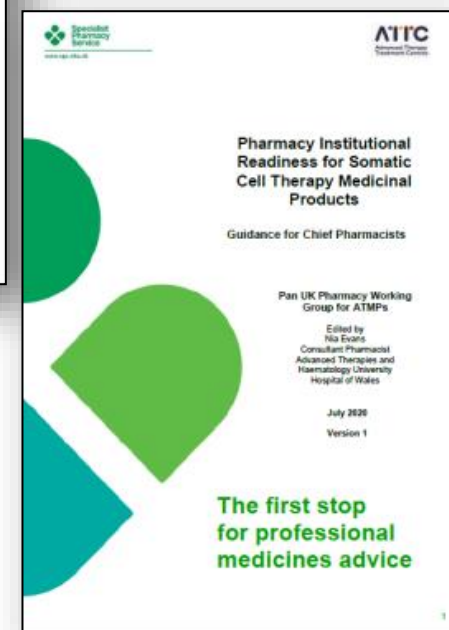
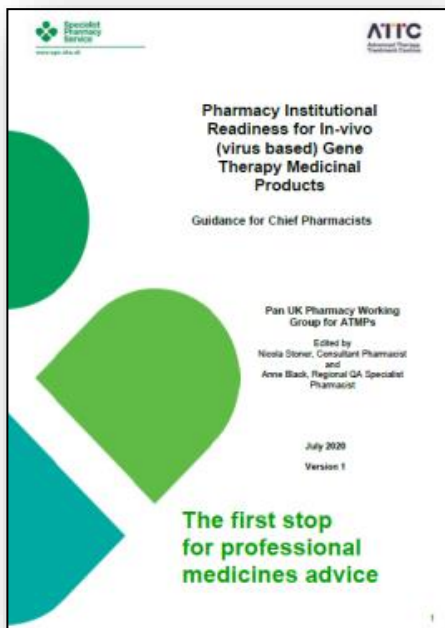
**Quality Systems**

**Collaboration &  
Communication**



# Pan UK Pharmacy Working Group for ATMPs

- Continuously improve information to aid safe and optimal implementation of ATMPs for patients
- 3 Subgroups - **Clinical/Operational**
  - Clinical Trials
  - Regulatory
- Pharmacy Institutional Readiness Documents  
<https://www.sps.nhs.uk/networks/pan-uk-pharmacy-working-group-for-atmps/>



# Operational Implementation

Map processes from  
placing order through to  
administration and  
monitoring of ATMPs

Key principles for each  
stage to facilitate  
consistency of  
implementation

# Pharmacy Institutional Readiness for In vivo Gene Therapy

## Product Receipt

- In-vivo (virus based) GTMPs are suitable for handling in Pharmacy. See [Gene Therapy and Preparation](#) for more information. On occasion they may require handling of dry ice and Pharmacy receiving areas require competency to undertake this activity.
- An SOP for receipt of GTMPs covering those holding marketing authorisation as well as investigational medicinal products (IMPs) is required. Checks on receipt should include integrity of the product, labelling, temperature compliance during transit, and Certificate of Analysis / QP certificates detailing the dose, if applicable. These should be reviewed by an appropriately trained clinical pharmacist or Clinical Trials pharmacist. Handling precautions should also be considered, including spillage kit when required.

An exemplar Product Receipt checklist is available in Appendix 5

## Storage

- Storage requirement is likely to be in -20°C to -90°C for GTMPs. Room temperature stability is often short.
- Continuous temperature monitoring and alarms are required from receipt through to administration. Actions in the event of an alarm should be specified (and in line with anything detailed in the supply agreement with the company/sponsor).
- Deviation processes should be clarified e.g. if short period temperature out-of-specification occurs, the SOP should state that risk assessment and actions to be taken are documented. Pharmacy should be made aware of any on-site storage deviations.

The exemplar Product Receipt checklist is available in Appendix 5 which covers aspects of storage

## Preparation Location Decision

- Some in-vivo GTMPs will require a thaw/preparation/reconstitution step. Optimal location for in-vivo gene therapy will be as per SmPC or clinical trial protocol. Where the location is not specified guidance can be found in [Gene Therapy and Preparation](#). Preparation location should have been defined in the GMSG risk assessment. Where stability data allows aseptic preparation should occur within a pharmacy aseptic unit.

Appendix 5

### In-vivo GTMP Receipt Checklist

Product Name	
Supplier	
Manufacturer (if different to above)	
Courier Job Number (& other ref no)	
Date & time received	
Received by	
Checking step	
Tamper-evident ties intact?	
Dry ice competency	
Transit Logger temp on receipt as per r	
Data Logger W (no alarms)	
All require Shippin Return Cert/	

Appendix 6a

### In-vivo GTMP Pharmacy Aseptic Preparation Checklist

Process Set Up/Governance		Yes / No / NA	Checker Initials	Date & time
Roles and responsibilities documented		Yes / No		
Dedicated Isolator or BSC (II) available		Yes / No / NA		
Preparation Location Complies with the requirements in Chart 8.2 in <a href="#">Gene Therapy and Preparation</a>		Yes / No / NA		
Worksheet written in line with SmPC, or Protocol / Pharmacy Manual (for Clinical Trials)		Yes / No / NA		
Appropriate label designed		Yes / No		
Worksheet approved		Yes / No		
Waste pathway clear		Yes / No		
Required PPE is available		Yes / No		
Cleaning agent appropriate		Yes / No		
Transport to clinical area SOP in place		Yes / No		
Spill kit available at all times		Yes / No		
Process		Yes / No	Checker Initials	Date & time
The process is covered by a suitable validation		Yes / No		
Operators are trained in the process		Yes / No		
SOP requires confirmation of patient readiness prior to beginning		Yes / No / NA		
Retrieval from storage (SOP available)		Yes / No / NA		
Thaw SOP in place		Yes / No / NA		
Check and release processes in place		Yes / No		
Transportation arranged		Yes / No		
Print Name				
Signature				
Date				

# Reflections

## What has gone well?

- Pharmacy Working Group
- Collaboration with ATTCs/CGTC
  - More Institutional Readiness work ongoing
- Commissioning
- Implementation



# Reflections

## What needs further improvement?

- Wider collaboration beyond ATTCs
- Greater signposting re commissioning of ATMPs for developers
- Greater NHSE clarity re commissioning for providers
- Streamlining for scale out

# Conclusion

- ATMPs are Exciting for Patients and for NHS
- ATMP implementation is challenging for NHS
- Getting it Right First Time requires Organisational Governance and System Leadership



**Thank you for listening**

**Does anyone have any  
questions?**

*Healthcare is a very busy - with a personal touch*