



Workshop Session



Advanced Therapy Medicinal Products & Medicines Governance

Anne Black

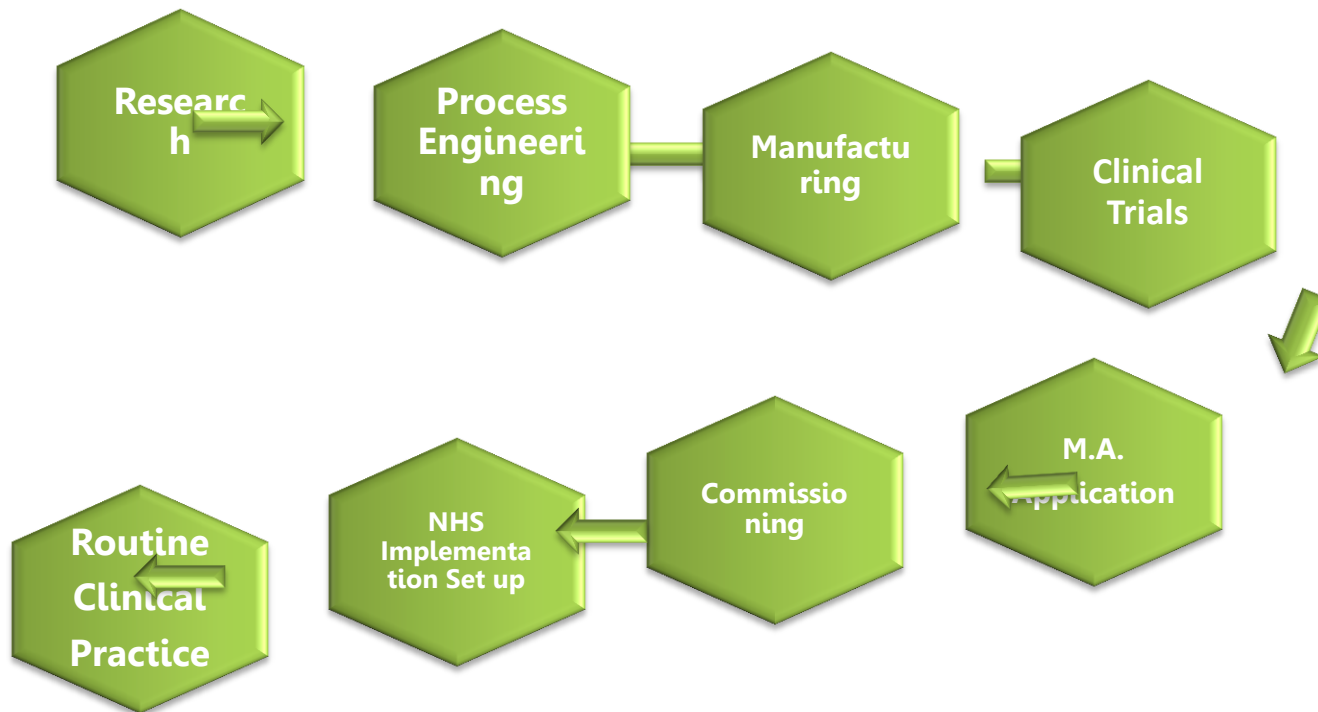
Regional QA Specialist Pharmacist- North East and Northumbria

ATMPs - Governance Aspects

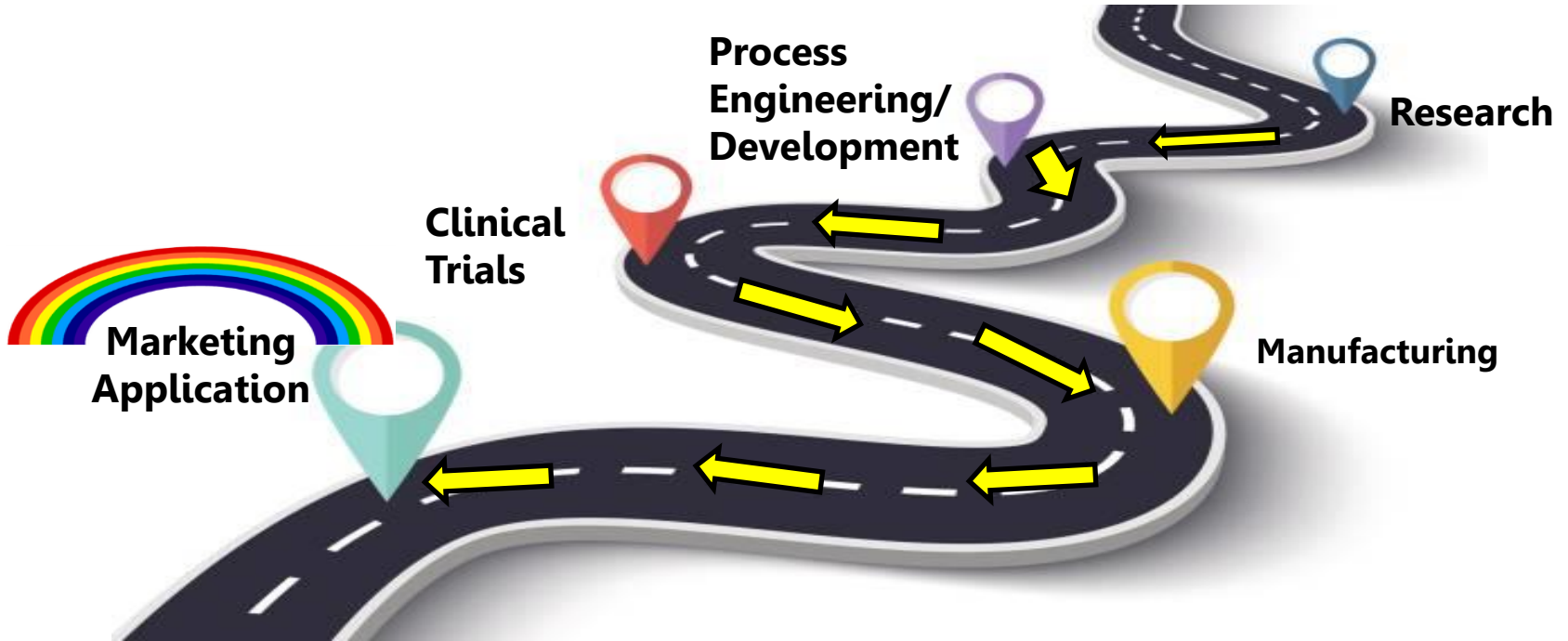
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'Cradle to Grave' ATMP Journey



Developers Journey



**What keeps patients safe?
Regulatory Controls: GMP & GCP
Clinical trials risks controlled if key stakeholders are engaged.**

Implementation Journey

Marketing
Authorisations

NHS
Implementation
Set Up

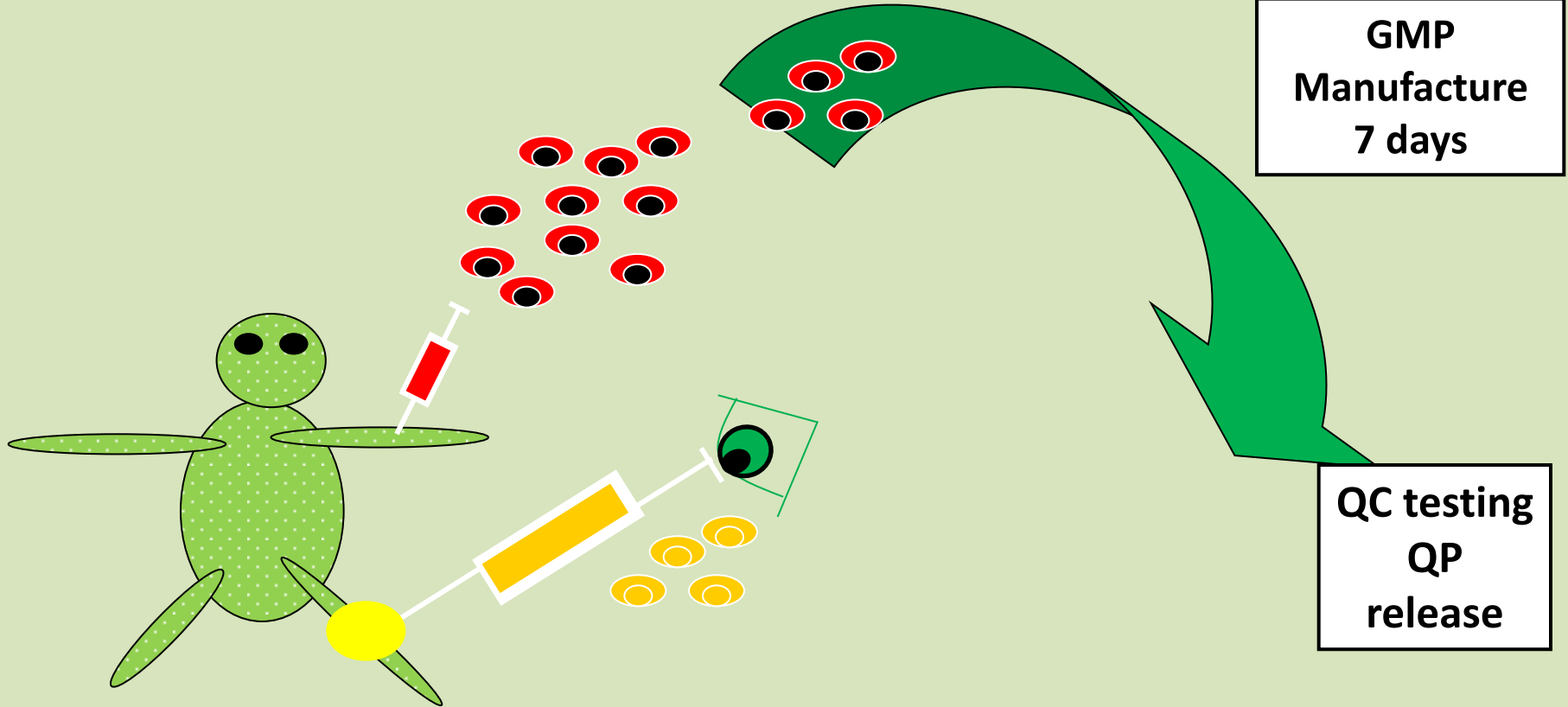
Commissioning
- NICE
- NHSE

Routine Clinical
Practice
- Patient Benefits

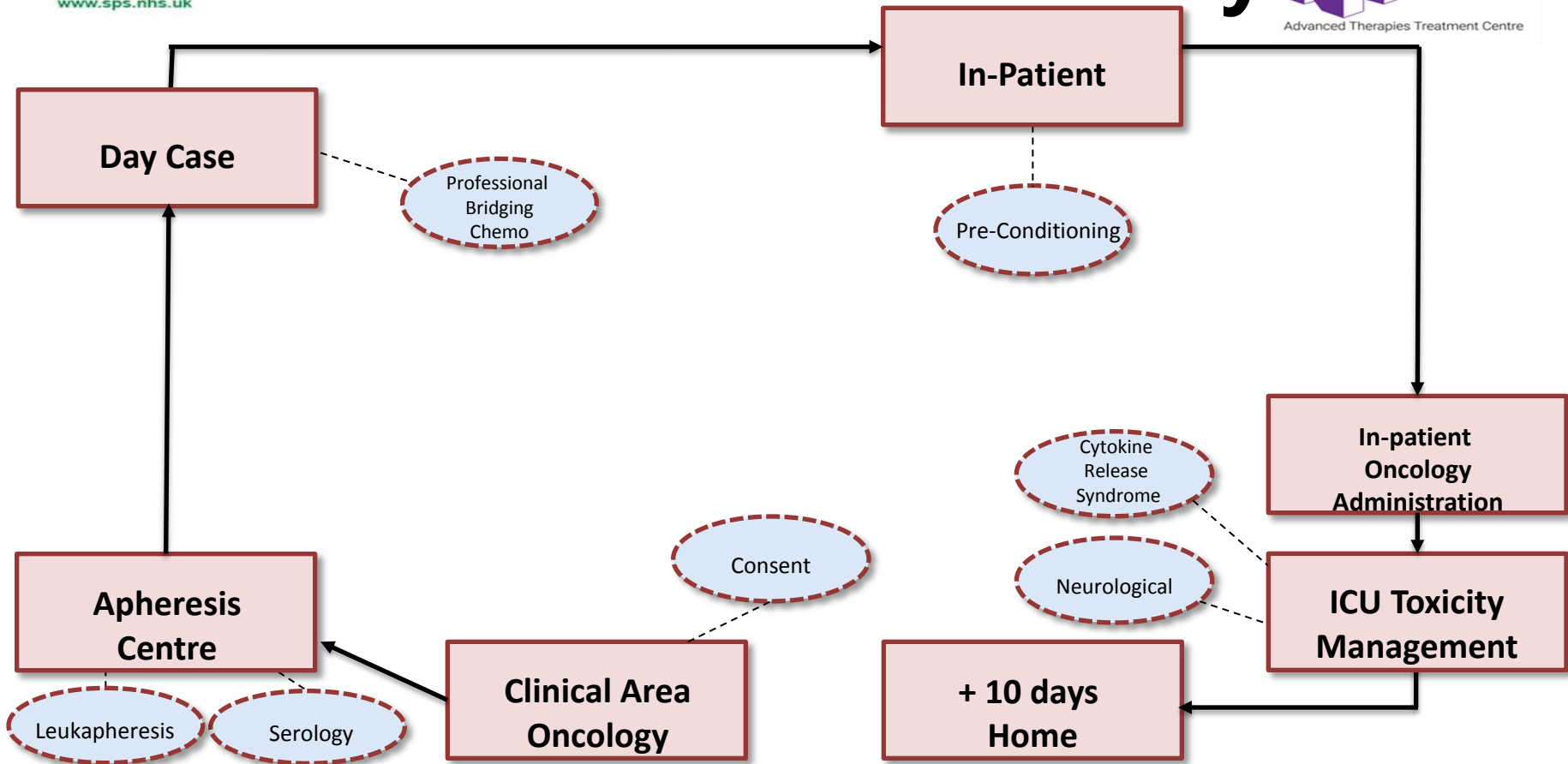
**What keeps Patients Safe?
Less Clear – SPC?
Limited experience in NHS
High Risk Medicines – Governance Required**

The Patient Perspective

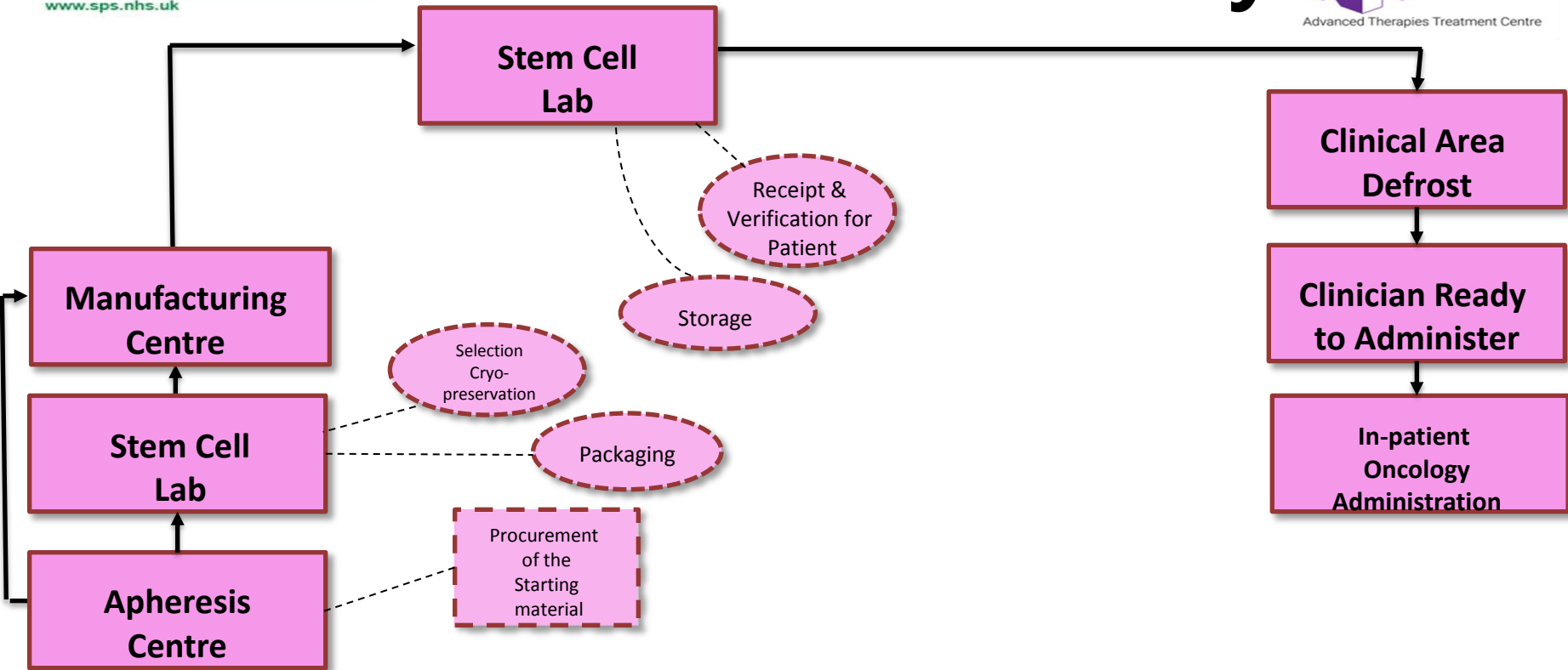
Personalised Medicine



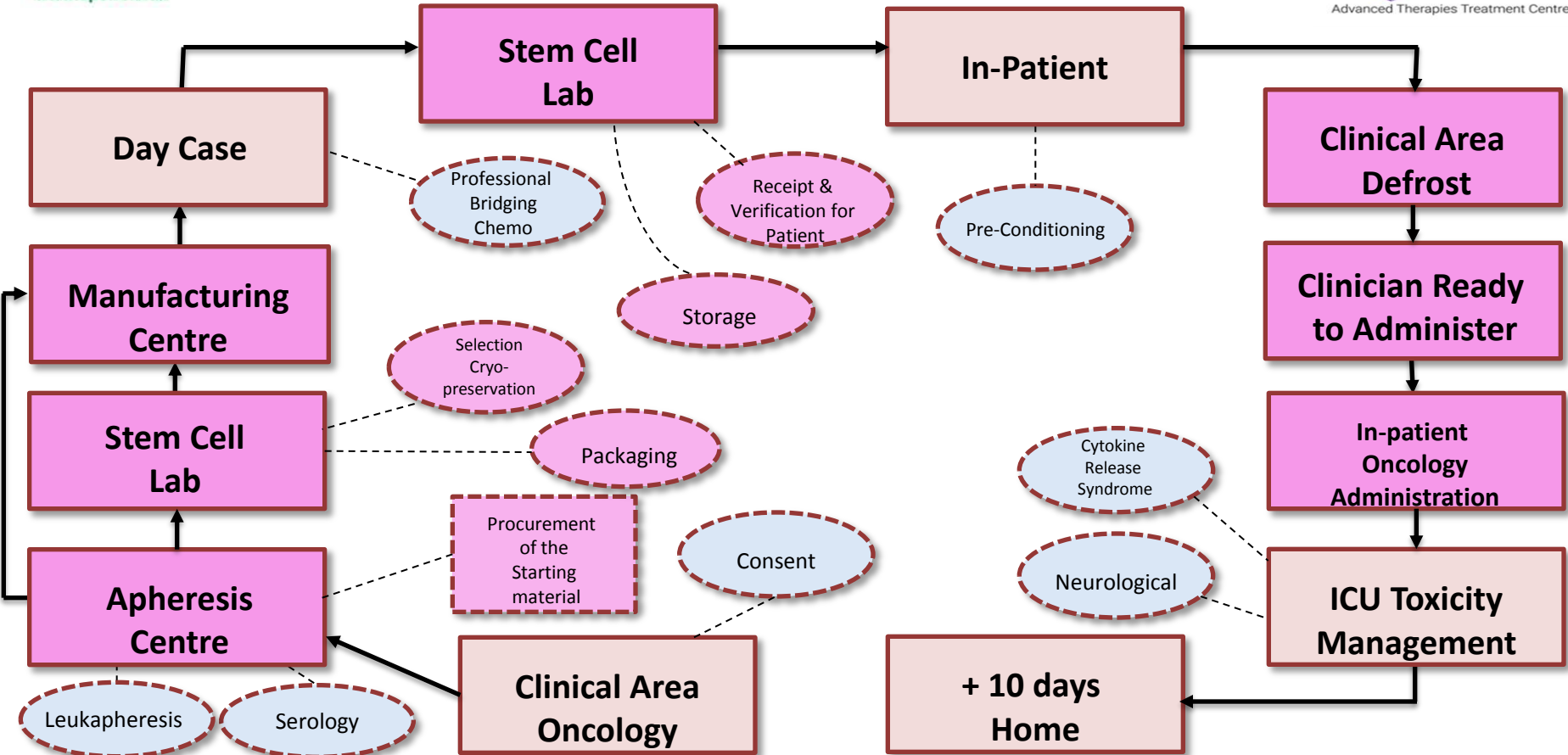
CAR-T Patient Journey

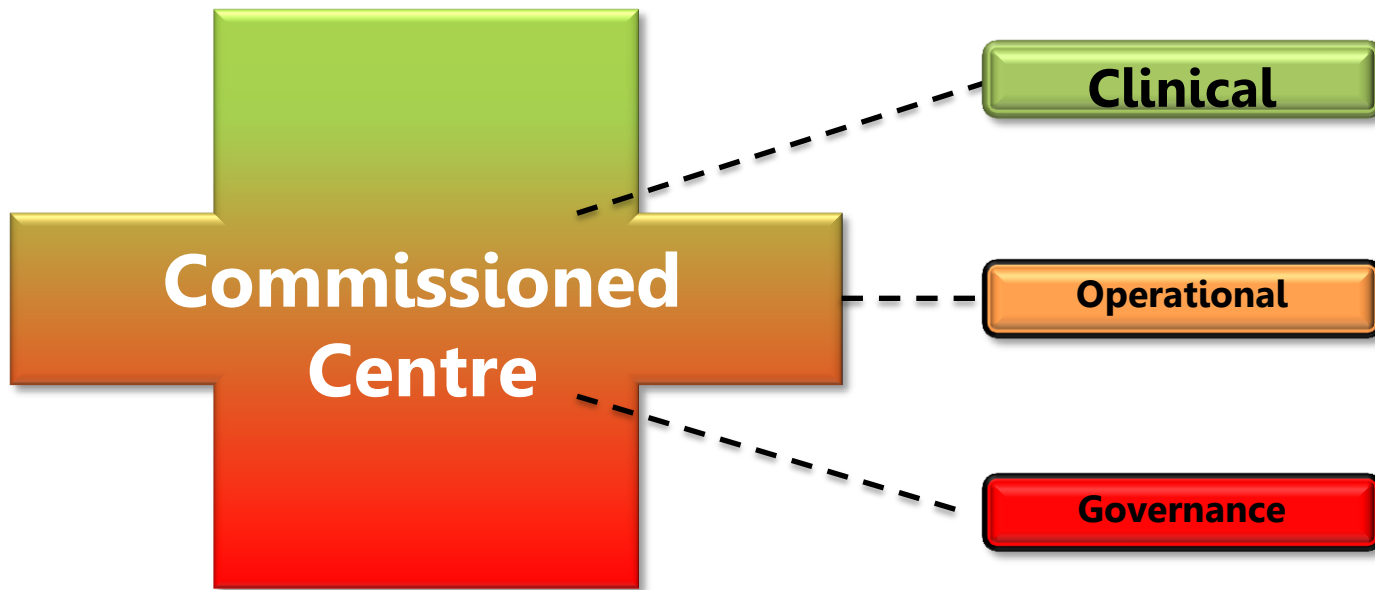


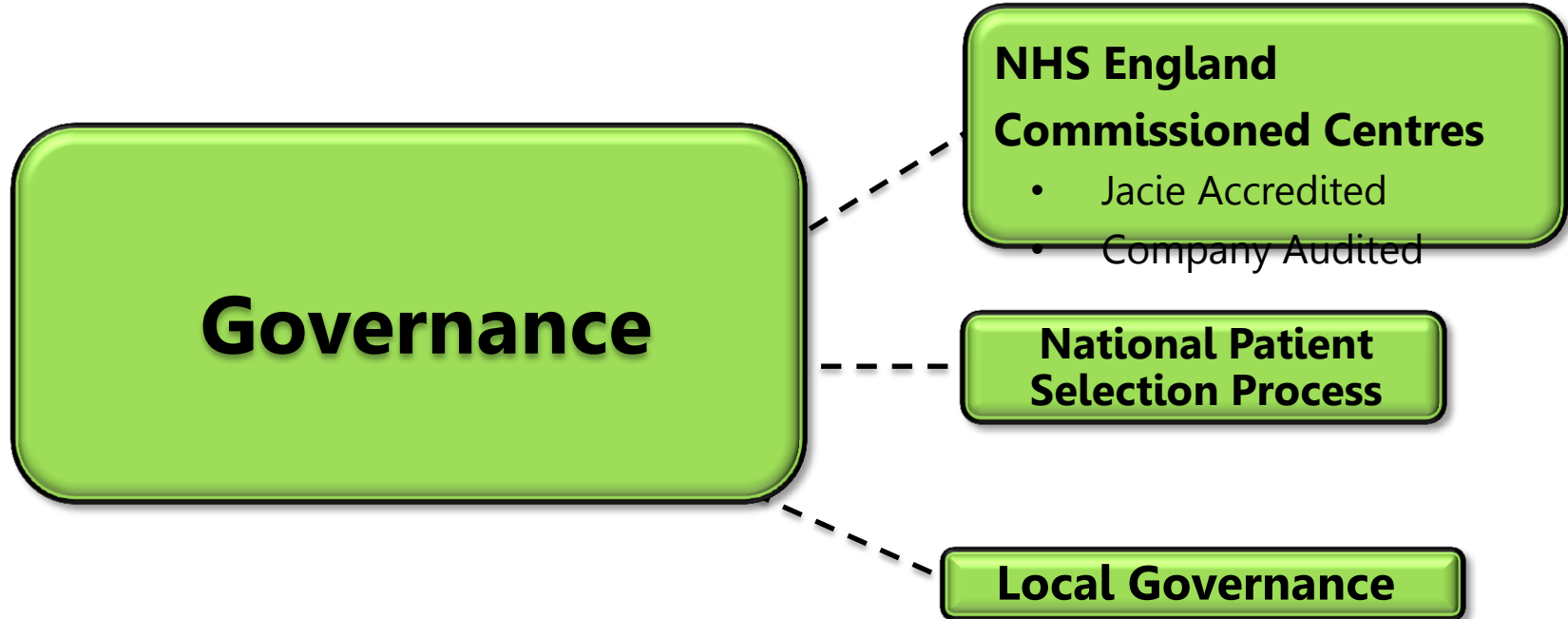
CAR-T Product Journey



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

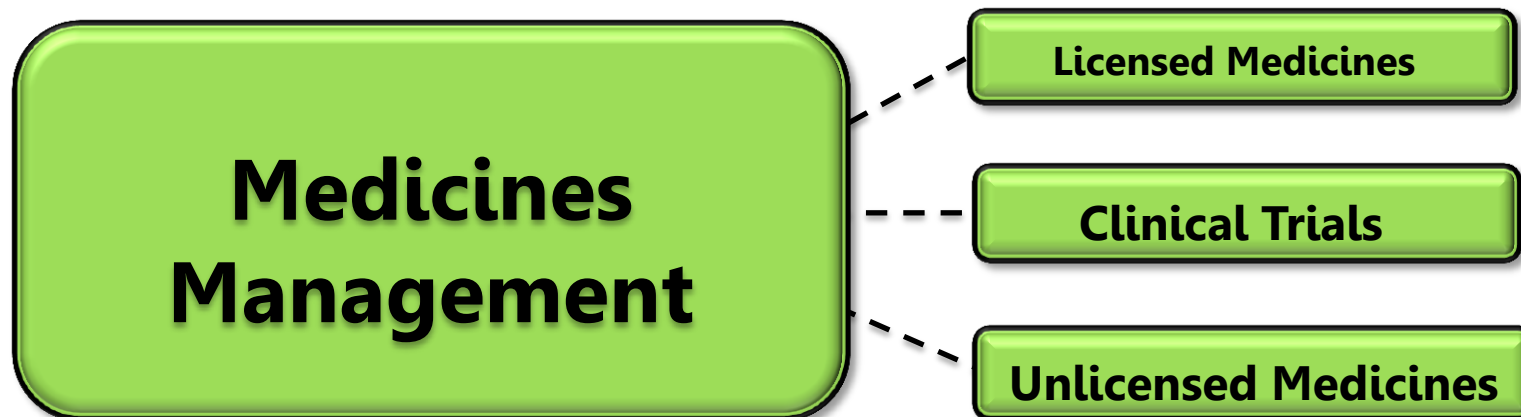
Edition 1

February 2017



Other Aspects

- Communication
- Interfaces
- Primary Care
- Media



Clinical Trials

Approvals

- Medicines Management/
D&T/R&D

Implement via Protocol

Unlicensed Medicines

Add ATMP to ULM Policies

Licensed CAR-T Therapy

Financial

- High cost drugs

Committees

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

Regulatory

- HTA (JACIE) MHRA

Autologous ATMP Medicine Management

Novel Medicine

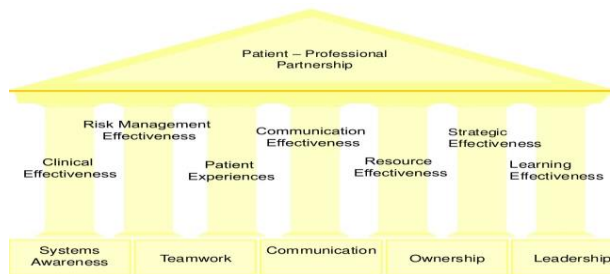
- Pharmacovigilance
 - Yellow card scheme
- Unlicensed Aspects

High Cost Drug

- Financial monitoring

Bespoke Therapy

- Deviations
- Cancellations
- Recalls



<https://www.gov.uk/government/publications/newborn-hearing-screening-programme-nhsp-operational-guidance/4-clinical-governance>

Clinical Governance

'A framework through which NHS Organisations are accountable for continuously improving the quality of services and creating an environment in which excellence will flourish'

Clinical Pharmacy

Patient Verification

Toxicity Management

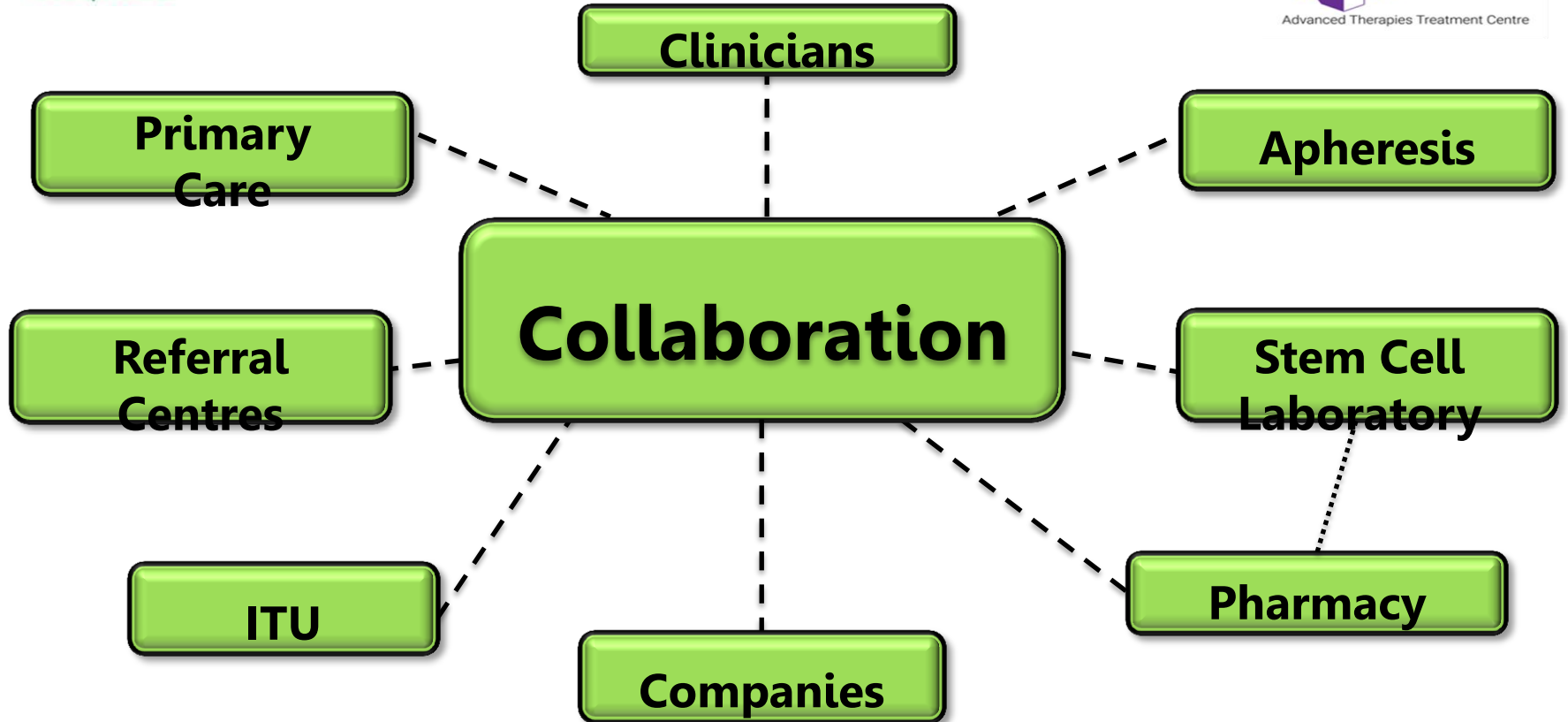
How to Assure Governance is Appropriate

Organisational Policies

Local Procedures

Quality Systems

**Collaboration &
Communication**



Pan UK Pharmacy Working Group for ATMPs

- Continuously improve information to and safe and optimal implementation of ATMPs for patients
- 3 Subgroups - **Clinical/Operational**
 - **Clinical Trials**
 - **Regulatory**
- 18 work streams including:

Pan UK PWG for ATMPs

- Define the role of a clinical pharmacist in the delivery of CAR-Ts with a checklist developed to ensure consistency.
- Draft National SOP templates covering: toxicity management, CRS, supporting meds for CAR-Ts, CAR-Ts now in specification, and their use as unlicensed medicines.
- Development of standardised clinical trial checklists for ATMPs that would be suitable for each of the phases of a study (e.g. feasibility, pre-initiation, SIV, study execution and completion.)
- Development of a standardised pharmacy manual checklist or template for studies with ATMPs.
- Draft document with a high-level view on legal requirements for Pharmacist Supervision of ATMPs.
- Produce guidance on governance requirements and preparation facilities required for the provision of gene therapy in healthcare establishments.

Reflections

What has gone well?

- Pharmacy Working Group
- Collaboration with ATTCs/CGTC
- Commissioning
- Implementation

Reflections

What needs further improvement?

- Wider collaboration beyond ATTCs
- Greater signposting re commissioning of ATMPs for developers.
- Greater NHSE engagement re role of pharmacy.
- Streamlining for scale out.

Conclusion

- CAR-T are Exciting for Patients and for NHS
- Getting it Right First Time requires Organisational Governance and System Leadership



Thank you for listening

**Does anyone have any
questions?**