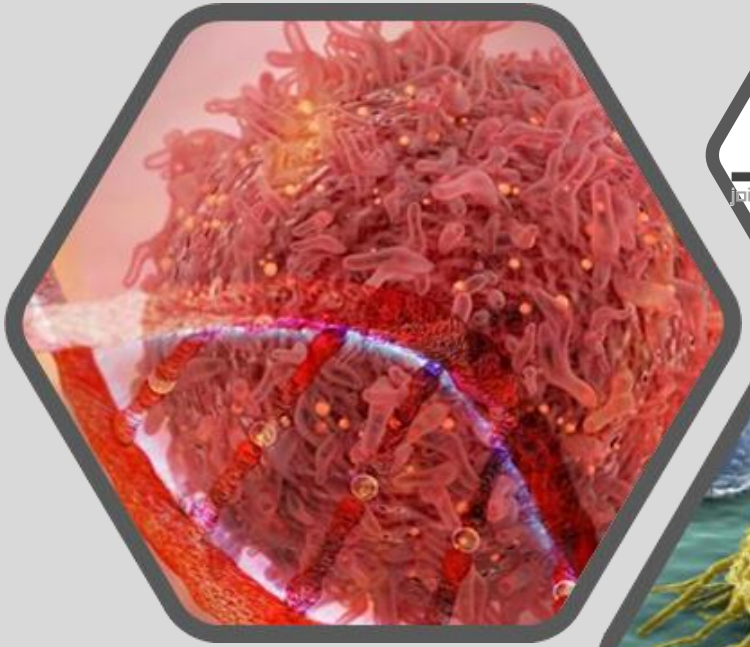

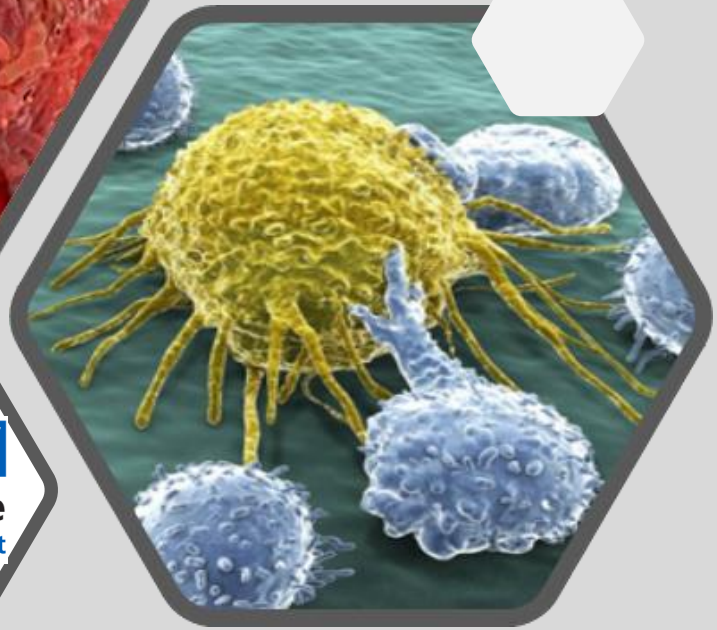

JACIE readiness for immune effector cells

Simon Cliffe

Quality Manager

The Christie NHS Foundation Trust

Contents

JACIE

- What, why and how

Immune effector cells

- What they are and their demands

JACIE and IEC's

- Standards and their importance

Present and future models

- Christie experience
- Future landscape

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What is JACIE

- Internationally agreed standards of care for haematology stem cell transplantation and cellular therapy
  - Clinical
  - Collection
  - Processing
  - 4 yearly cycle
  - Quality standards

Why JACIE

- Demonstrates best practice
- Improves patient outcomes
- Demonstrates quality service to:
  - Patients
  - Researchers
  - Pharmaceutical sector
  - Commissioners

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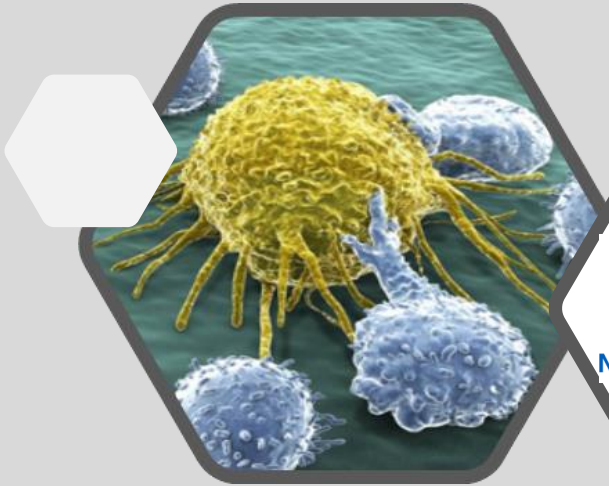
Demonstrating compliance

- Quality management system
  - Policies and SOPs
  - Training
  - Audits
  - Incidents and deviations
  - Change control
- Governance Structure
- Keeping practice up to date
  - Clinical trials
  - Update policies/SOPs every 2 years



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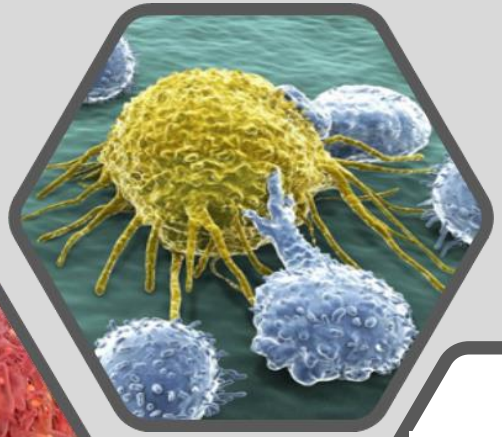
What are immune effector cells

- Cells used to modulate or elicit an immune response
  - dendritic cells
  - natural killer cells
  - B cells
  - T cells
    - Chimeric antigen receptor T cells (CAR-T cells)



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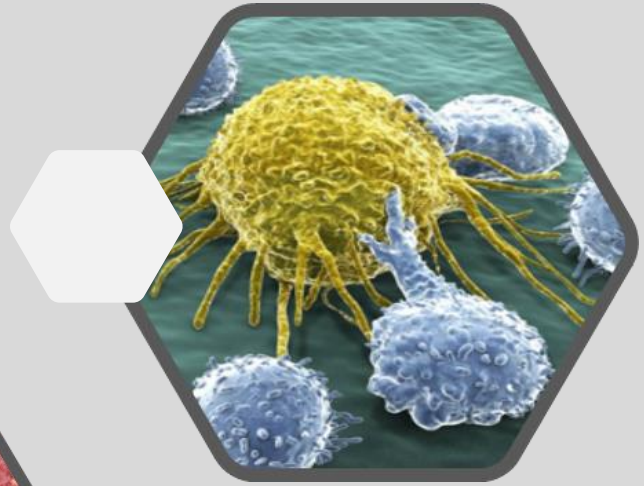
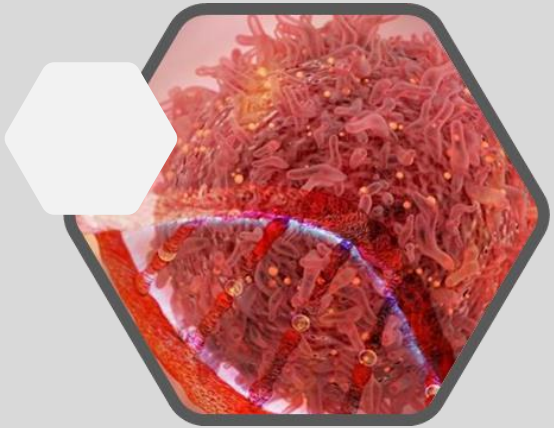
Immune effector cell demands

- Unique logistics
  - New systems
  - Increased chain of custody
- Unique toxicity profiles
- Other factors
- Regulators





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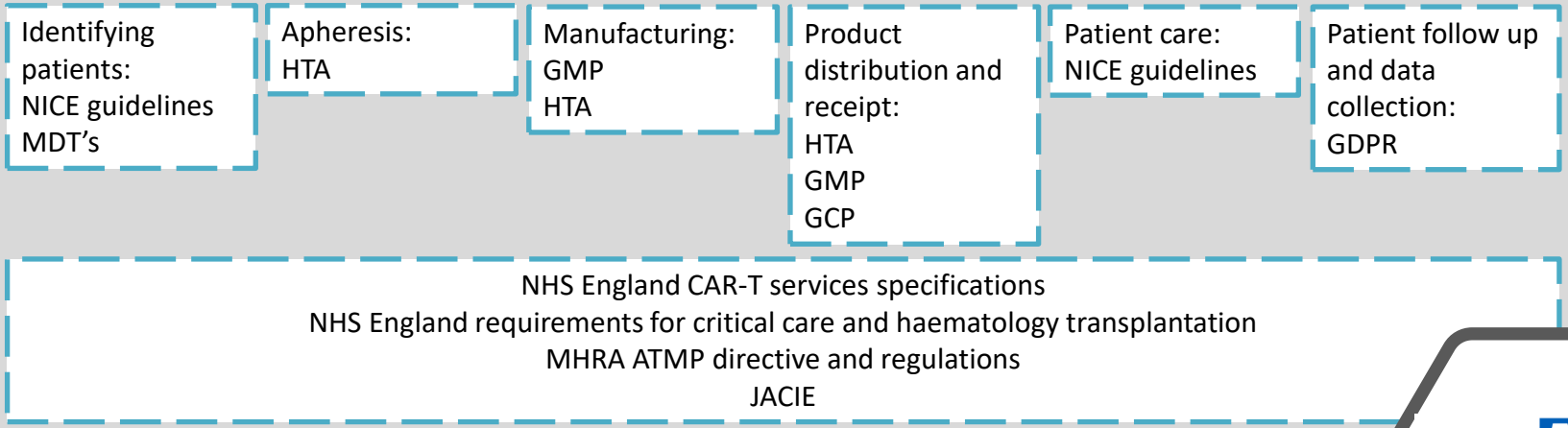
JACIE's immune effector cell standards

- Created in the US due to rapid progression of IEC therapies
- JACIE
  - Edition 6.01 incorporated into edition 7
  - CAR-T therapy
- Standards
  - 43 specific IEC standards
  - Chain of custody
  - Toxicity management – training and SOPs
  - Outcome and follow up reporting

Regulation considerations

Extensive regulations



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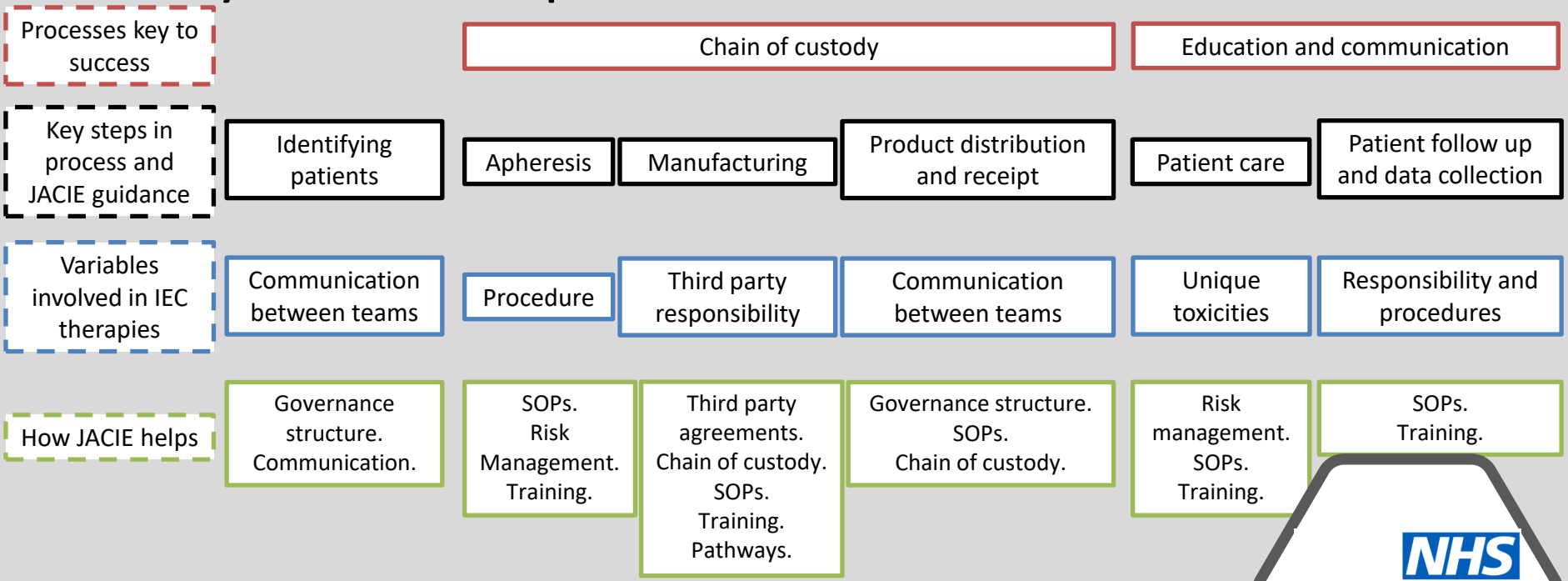
Why is JACIE important for immune effector cells



Adapted from: Maus et al. (2017) The why, what, and how of the new FACT standards for immune effector cells. Journal for ImmunoTherapy of Cancer pp 5:36.

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Current models of practice

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- NIHR Manchester Clinical Research Facility – JACIE clinical facility

- Process
  - Gap analysis

Current models of practice

- Key experiences
  - Shared learning
  - Education
  - Increased capacity
  - Specific trial understanding
  - Communication
- Why JACIE was important
  - Underpins requirements for IEC's
  - Governance and coordination
  - Key document requirements

May not be appropriate for all

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Future Landscape

* Definition (FACT-JACIE Standards, 7th edition):
Immune effector cell: A cell that has differentiated into a form capable of modulating or effecting a specific immune response. Immune effector cells derived from these sources, defined broadly as any cells, in vitro modified or not, that are capable of eliciting or modulating an immune response. This broad designation includes cellular therapy products with widely diverse manufacturing methods, constructs, clinical indications, and safety and toxicity profiles. Individual programs and responsible personnel must understand the immune effector cell products in clinical use, the spectrum and timing of potential and anticipated toxicities associated with each product or type of product, implement relevant evaluation and mitigation strategies, and apply these Standards appropriately to each situation.
Note that Donor Lymphocyte Infusions (DLI) are not considered an IEC for these purposes

Questions			Applicant Answer
II - CLINICAL FACILITY			
1	Describe any participation in studies or clinical trails including the number of subjects.		
2	List IEC products	List any IEC products (excluding DLI) including in studies or trials (commercial and/or academic) : IECs type	
		List any IEC products (excluding DLI) including in studies or trials (commercial and/or academic): Manufacturer	
3	Pharmacy, storage and delivery	Describe the role of the pharmacy in administration of IEC	
		Describe the system(s) in place to handle those IEC products supplied frozen at cryogenic temperatures	
		Describe how cryogenic bags of IEC are thawed	
4	Key support services: Services supporting your clinical team		☐ HPC, Apheresis Facility
			☐ IEC product storage
			☐ Pharmacy service
			☐ Intensive Care Unit
			☐ Neurology Department

IEC	B3.3.4.18	Cytokine release syndrome.
IEC	B3.3.4.19	Tumor lysis syndrome and macrophage activation syndrome.
IEC	B3.3.4.20	Neurologic toxicity.
IEC	B3.3.4.21	Cardiac dysfunction.
IEC	B3.3.4.22	Renal dysfunction.
IEC	B3.3.4.23	Respiratory distress.
IEC	B3.3.4.24	Anaphylaxis.

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Future Landscape

- Edition 8 of the JACIE standards – March 2021
  - 2019 survey

- US model
  - Separate immune effector cell standards