

Introducing An Education Programme To Ensure CRF Readiness For ATMP Clinical Trials

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Aim/Purpose

The Christie Hospital is the lead organisation for one of three Advanced Therapy Treatment Centres (ATTCs) funded by Innovate UK. The iMATCH (Innovate Manchester Advanced Therapy Centre Hub) consortium aims to facilitate the scale up of delivery of Advance Therapy Medicinal Products (ATMPs) by making complex ATMP trials as easy to deliver as standard drug trials. Staff education and training form an integral part of achieving these objectives.

The following diagrams represent A) a CAR-T cell and its interaction with a tumour cell B) The process of a patients T cells being taken, engineered and re-infused.

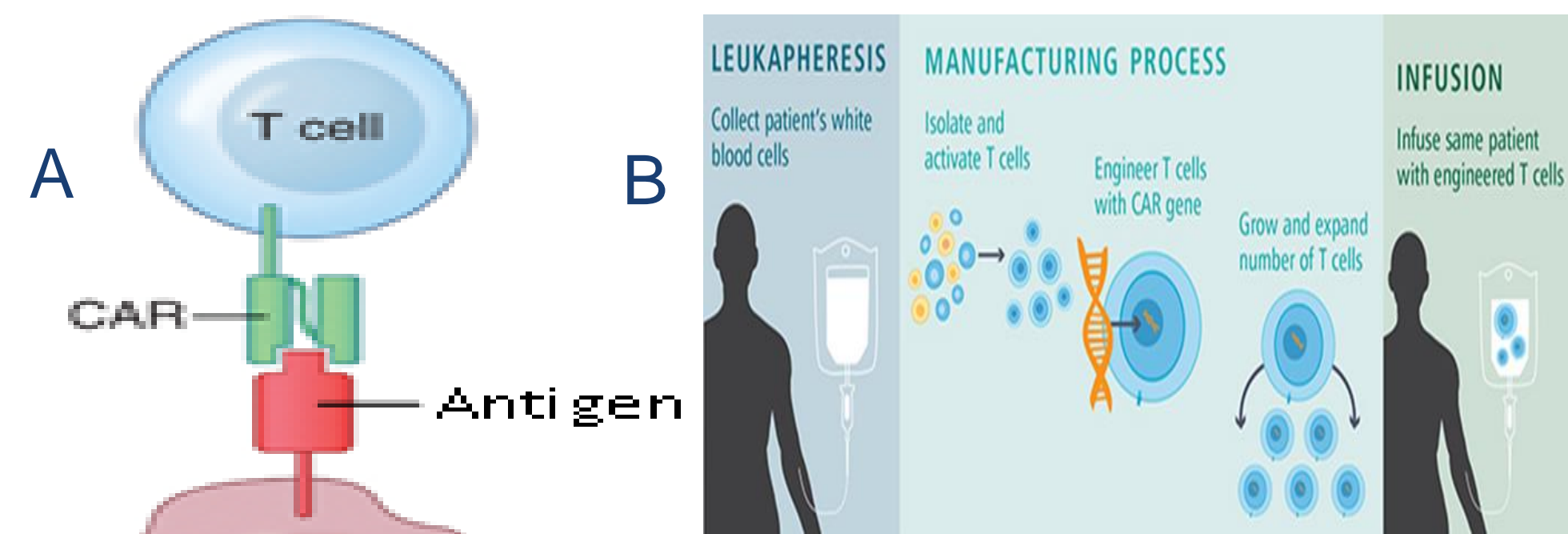
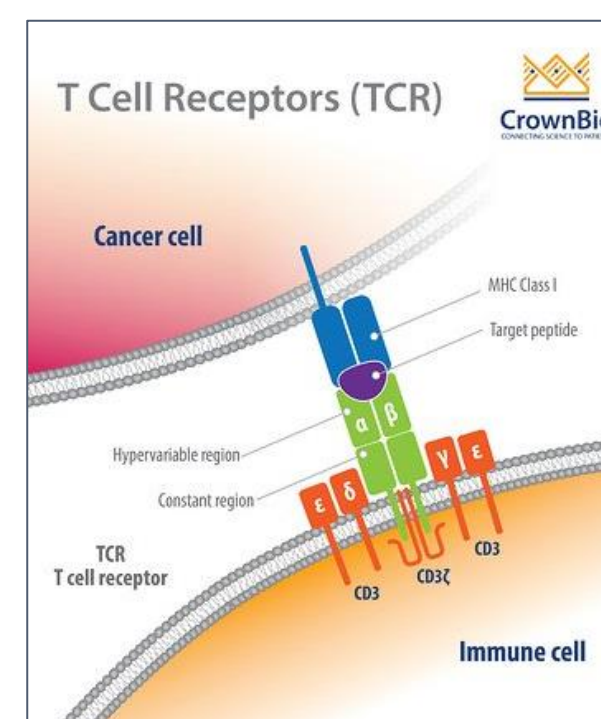


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Adapted from Hinrichs & Restifo Nat Biotech 2013

T Cell Receptor T Cells (TCR)

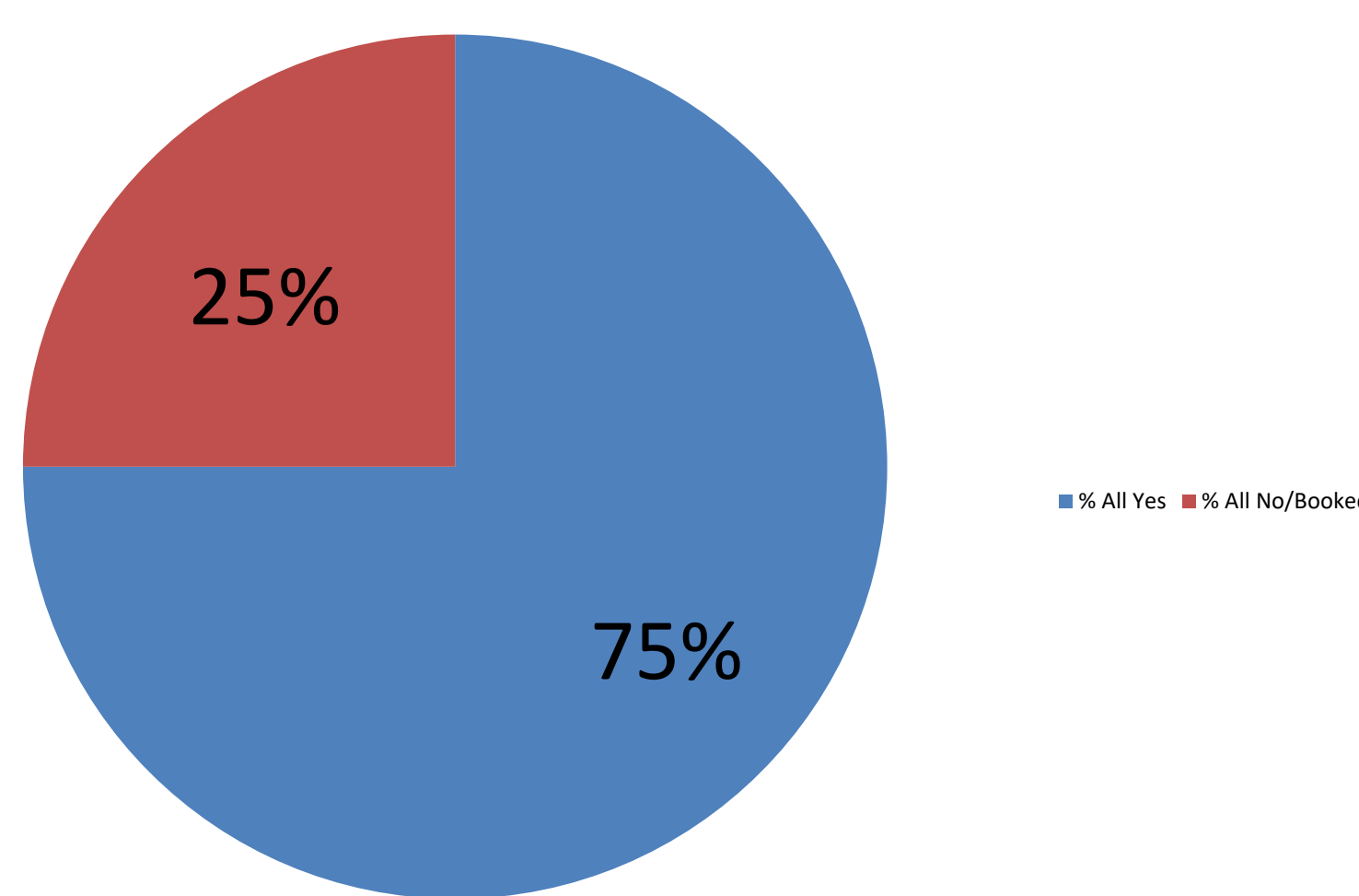
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Methodology

The Christie CRF has some early experience in delivering ATMP studies, however activity was sporadic therefore maintaining staff competence was challenging. With a growing ATMP trial portfolio, the appointment of an ATMP senior practice educator was seen as critical. This has facilitated the development of a comprehensive education programme which includes didactic and experiential learning. Implementation has been over 4 months, releasing 2-3 nursing staff every week for a series of lectures. Moreover, the programme includes specialist clinical placements with specific learning objectives and competencies using a self-directed workbook

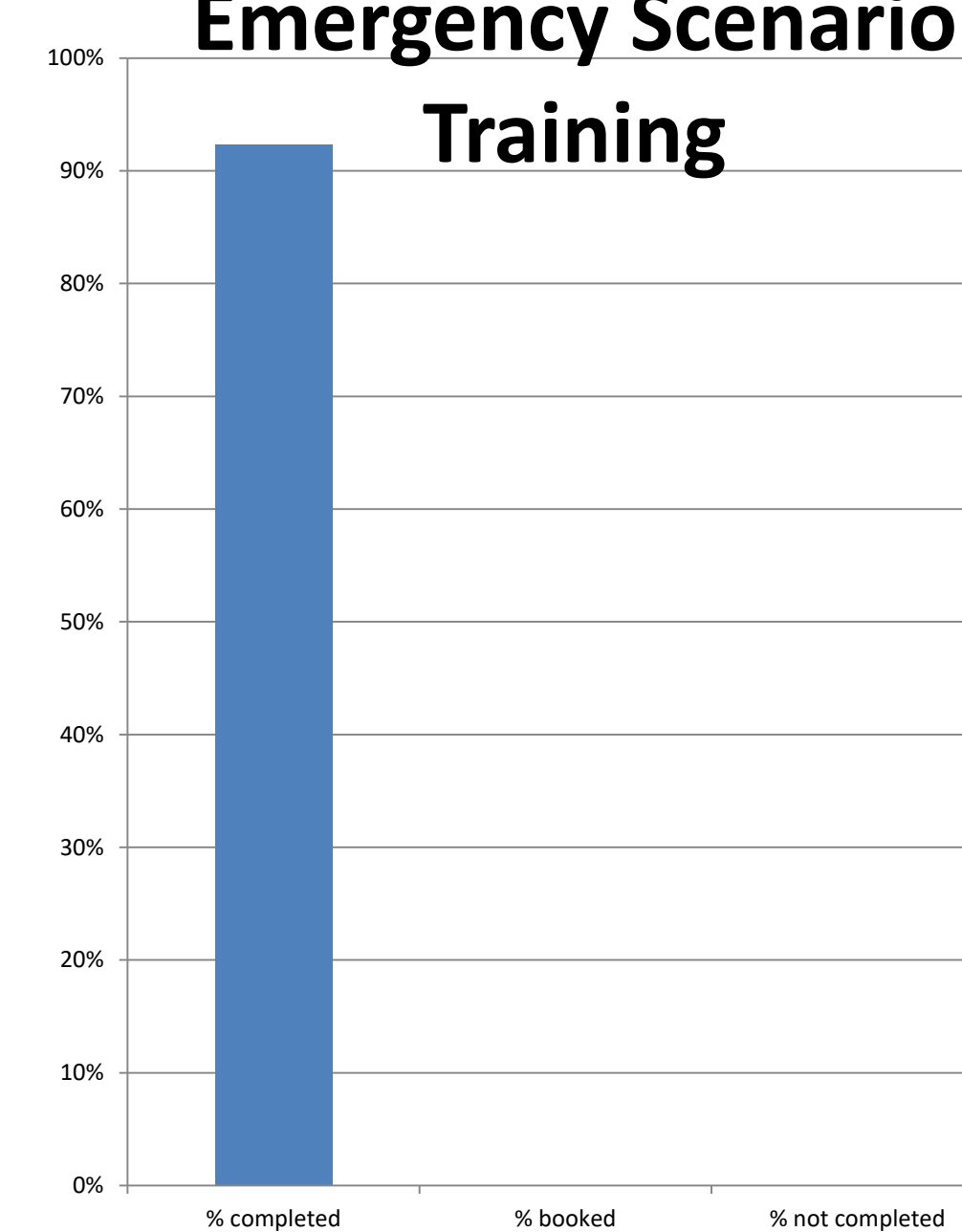
Priority Training



Contribution of CRF

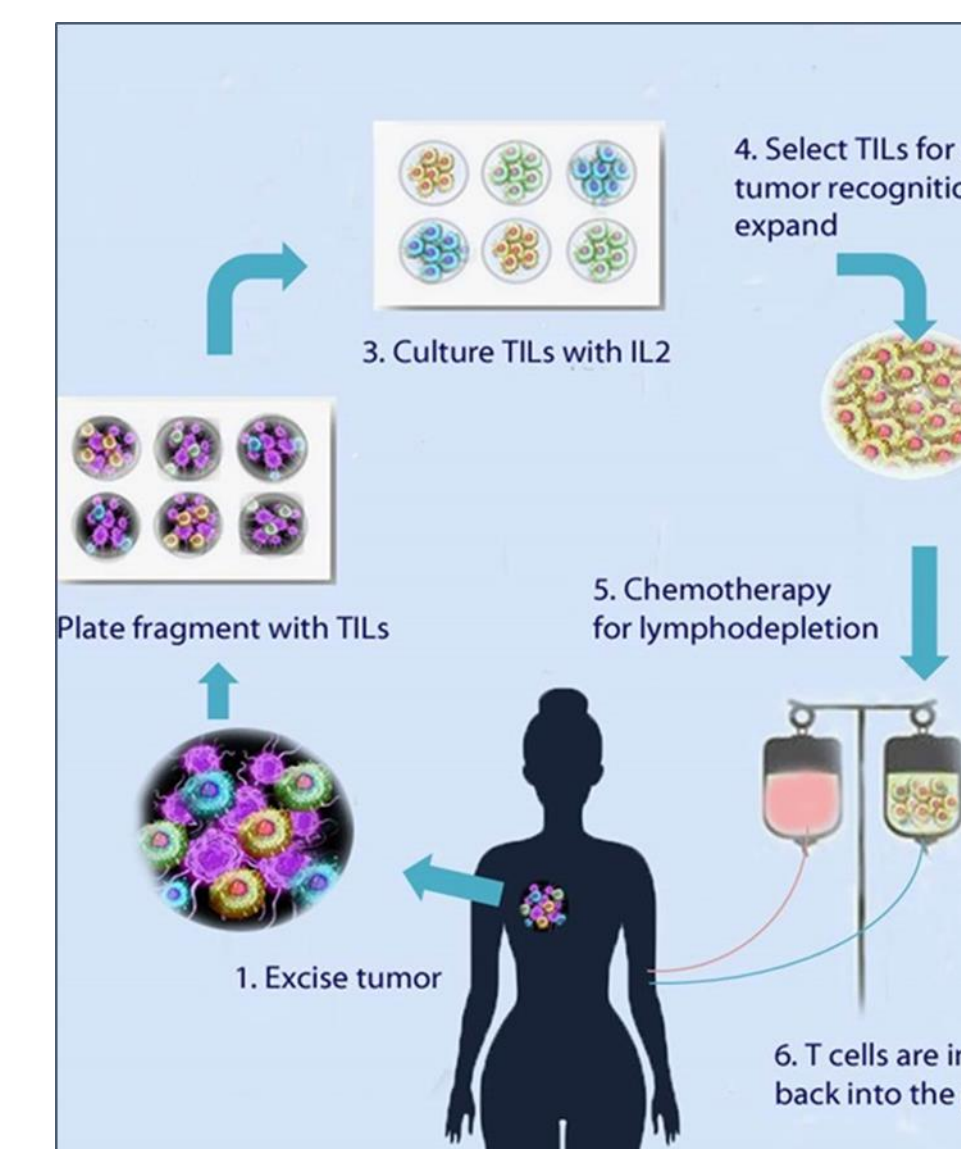
Improvements to clinical and theoretical knowledge are evident from staff feedback. Specifically, initiating Patient Group Directions for IV antibiotics, blood products, emergency training and in-depth awareness of ATMP toxicities have improved staff confidence levels.

Emergency Scenario Training



Tumour Infiltrating Lymphocyte (TIL)

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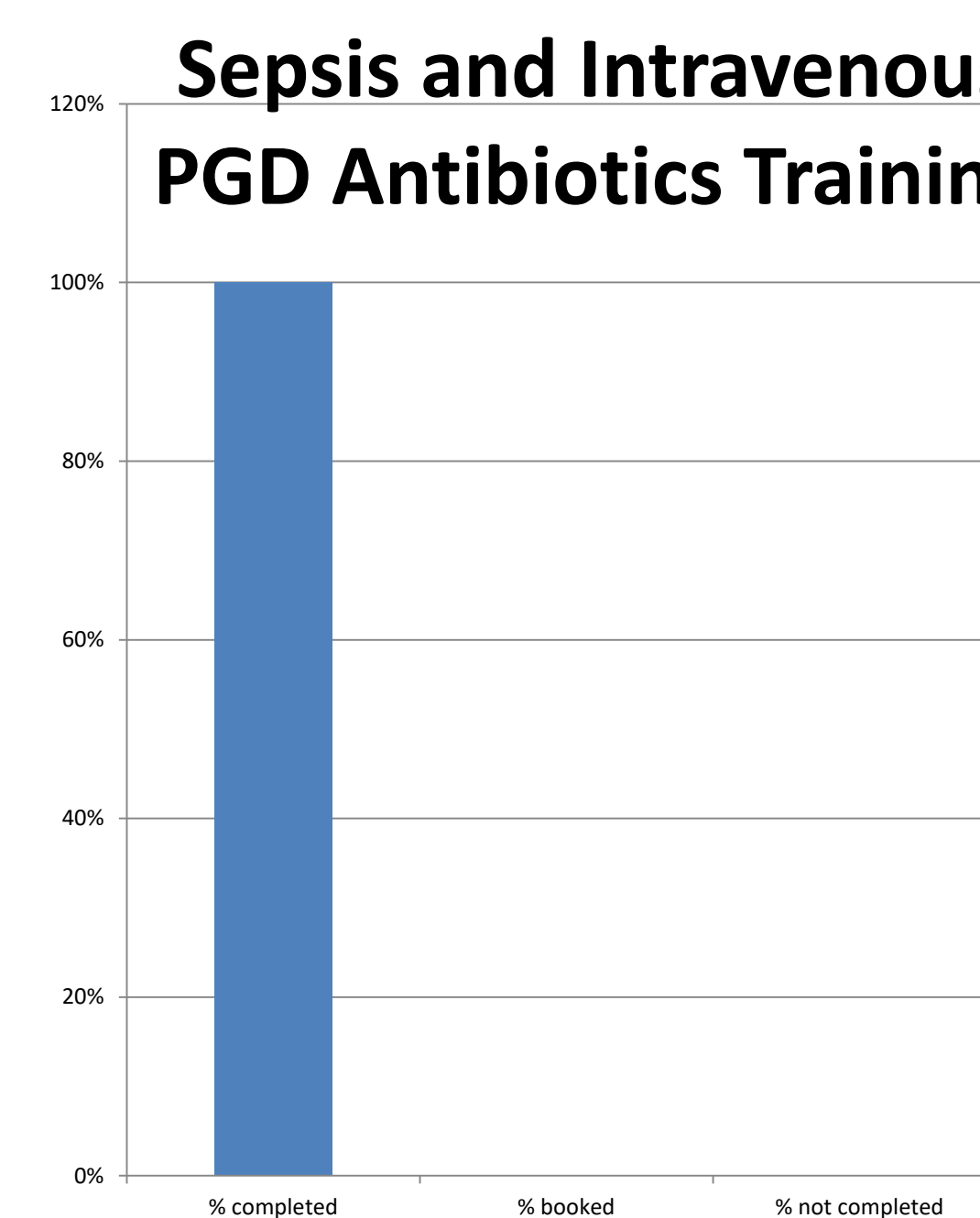
Results and Conclusion

While the ATMP education programme is in its infancy, early feedback indicates staff feel supported in the management of this complex group of patients. Evaluation is ongoing at weekly management meetings and through formal audit. The programme and results are shared monthly through the consortium to other CRF establishments and at national ATMP meetings.

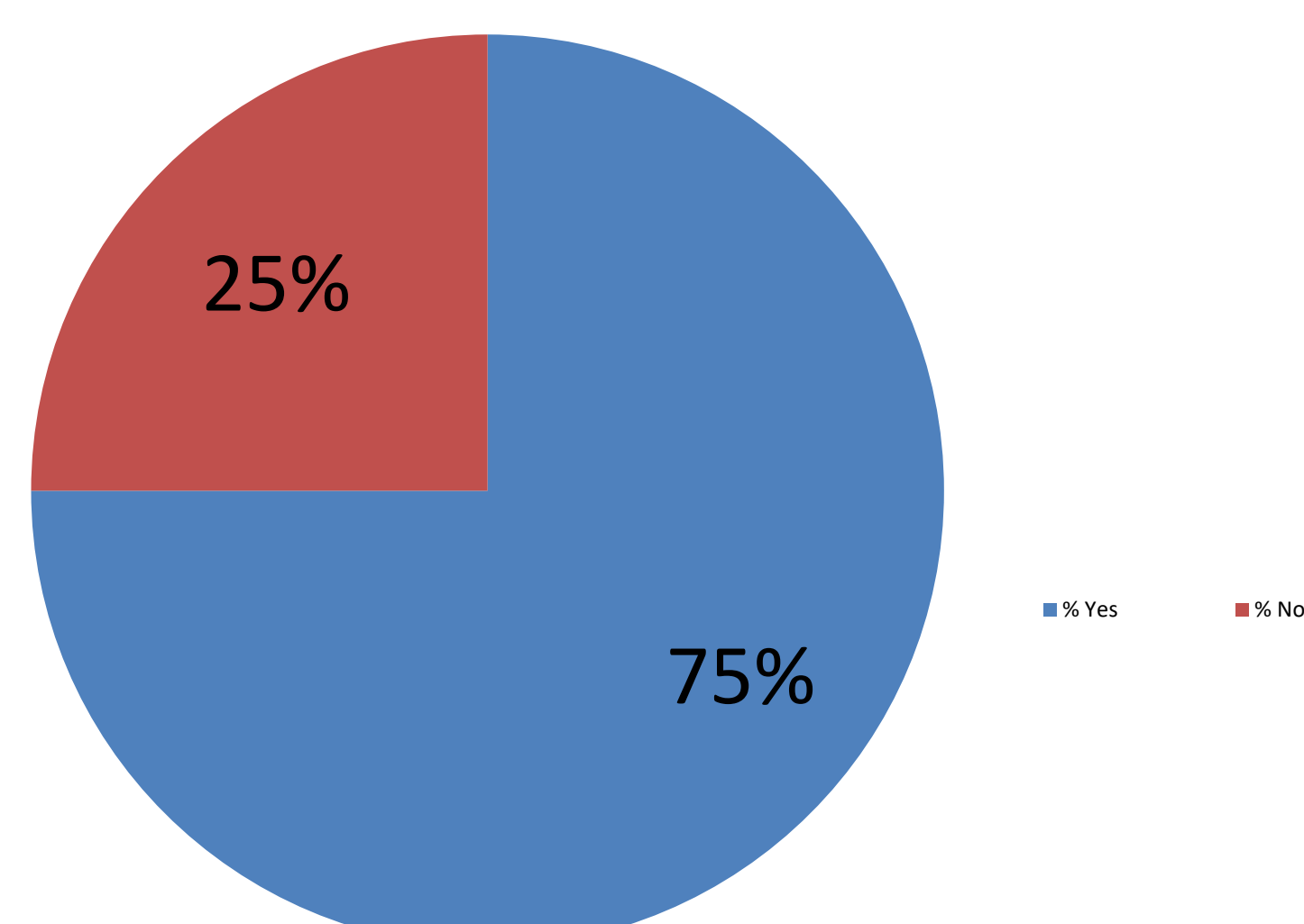
Priority Training for CRF Staff

- An Overview of Cellular Therapy
- Cytokine Release Syndrome
- Immune Effector Cell-Associated Neurotoxicity Syndrome
- Inpatient management of patients receiving immune effector cells
- Administration of preparative regimens including growth factors
- Prophylaxis and antifungals management
- Infusion of Cellular Products
- Emergency T-Cell Administration Training

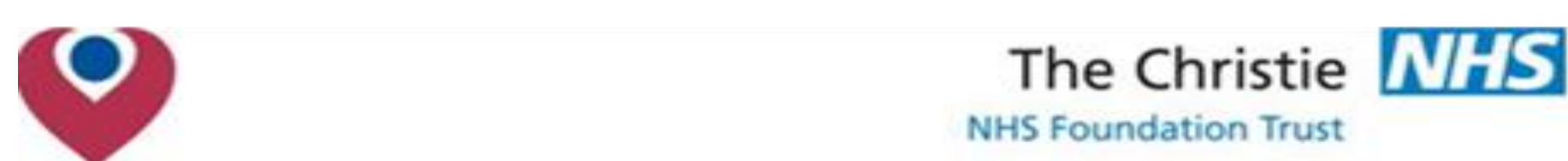
Sepsis and Intravenous PGD Antibiotics Training



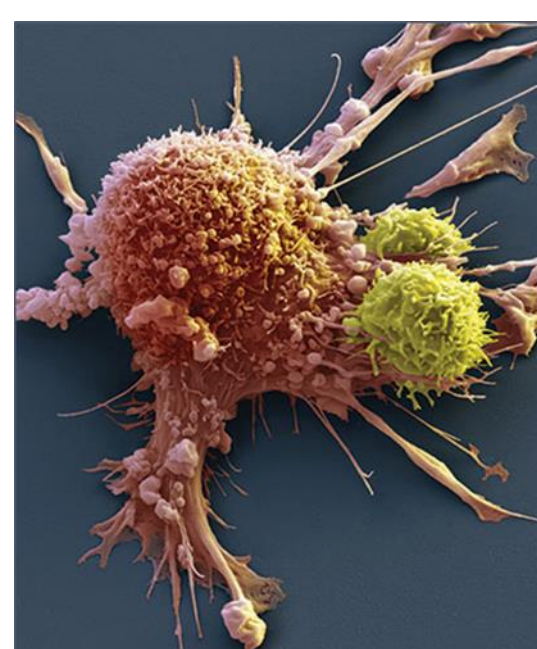
Attendance to the in-house Transplant and Cell Therapy Study Day



Cell Product being remove from dry shipping container



Immune Effector Cell Training Workbook



Picture from: Hamers, L. (2018) How to make CAR-T cell therapies for cancer safer and more effective. © Society for Science & the Public 2000 – 2019, Vol. 194, No. 1, July 7, 2018, p. 22.



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