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Implementation of ISBT 128 Labelling at Newcastle upon Tyne Hospitals Apheresis Unit.

Autolus

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Northern Alliance Advanced Therapies Treatment Centre

TERUMO

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This document reports on the ATTC network project to adopt a new labelling process within The Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH) to meet the most recent standards for apheresis products. This document will examine the lessons learned from the implementation of the STAFA labelling solution with the goal of supporting other NHS sites to develop their labelling capabilities.

Background

There has been a coordinated standardisation of blood product labelling since the publication of the International Society for Blood Transfusion (ISBT) 128 specification by the International Council for Commonality in Blood Banking Automation (ICCBA). It was recognised that the ISBT 128 standard would also provide the same Chain of Identity (COI) information required for effective traceability of advanced therapy products. COI and proper traceability are integral to the safe use of advanced therapies. They enable full visibility of cellular material as it is taken from donors and manufactured into medicinal products for administration to patients. This is crucial to safe and compliant use of advanced therapies.

The ISBT 128 Standard Labelling of Apheresis Collection Products for Sponsor Cellular Therapy Manufacturing was published in December 2020. It was intended to support facilities, label vendors, and software developers in the design and use of appropriate ISBT 128 labels for cellular therapy products. The guidance provides instruction on labelling in line with:

- ST-018 – ISBT 128 Standard Labeling of Collection Products for Cellular Therapy Manufacturing
- ST-028 – ISBT 128 Standard Chain of Identity (CoI) Identifier
- ST-001 – ISBT 128 Standard Technical Specifications
- ST-002 – ISBT 128 Standard Terminology for Medical Products of Human Origin
- ST-004 - ISBT 128 Standard Labeling of Cellular Therapy Products
- IG-045 – Implementation Guide: Applying ISBT 128 Labels to Collection Products for Further Manufacture
- IG-050 – Implementation Guide: Using the ISBT 128 Chain of Identity Identifier (DRAFT - Public comment period coming soon)

Problem Statement

Due to capacity and infrastructure constraints at NHS sites, the implementation of ISBT 128 standard labelling for apheresis products has been low. In response to the adoption of Chimeric Antigen T-cell Receptor Cell Therapies (CAR-Ts), many sites across the United Kingdom (UK), have changed the labelling of apheresis products to meet regulatory requirements but have not been able to meet the ISBT 128 standard. The methods employed at sites across the UK therefore vary, resulting in non-standardised final labels being used.

It was proposed that the ISBT 128 Standard Labelling of Apheresis Collection Products for Sponsor Cellular Therapy Manufacturing (ST-018) be implemented at a key UK clinical site as an exemplar from which learnings could be disseminated; demonstrating use of best practice for labelling of cell and tissue products for onward manufacture to ATMPs. NUTH agreed to take part in this exemplar exercise.

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Original Practice

Below is an illustration of the labelling practice employed by NUTH; the generation of ISBT Donor Identification Numbers (DIN) was performed outside the apheresis unit and sent to the unit before the final label was assembled, affixed, second checked and the product distributed. The labels were handwritten by the nursing team.

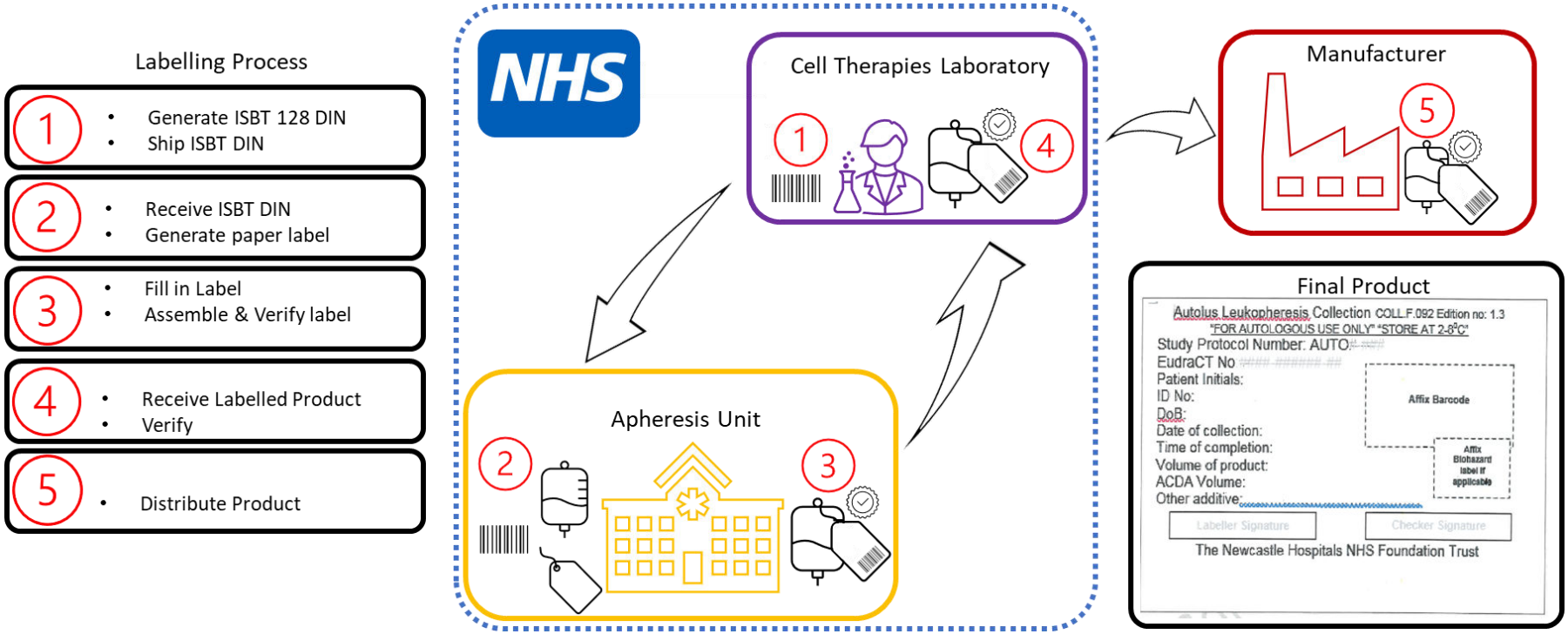

Figure 1.Existing Labelling Practice at NuTH

ISBT 128 compliant practice

The newly implemented labelling practice at NUTH, enabling the apheresis unit to produce fully compliant ISBT 128 labels at the bedside, is illustrated in Figure 2.

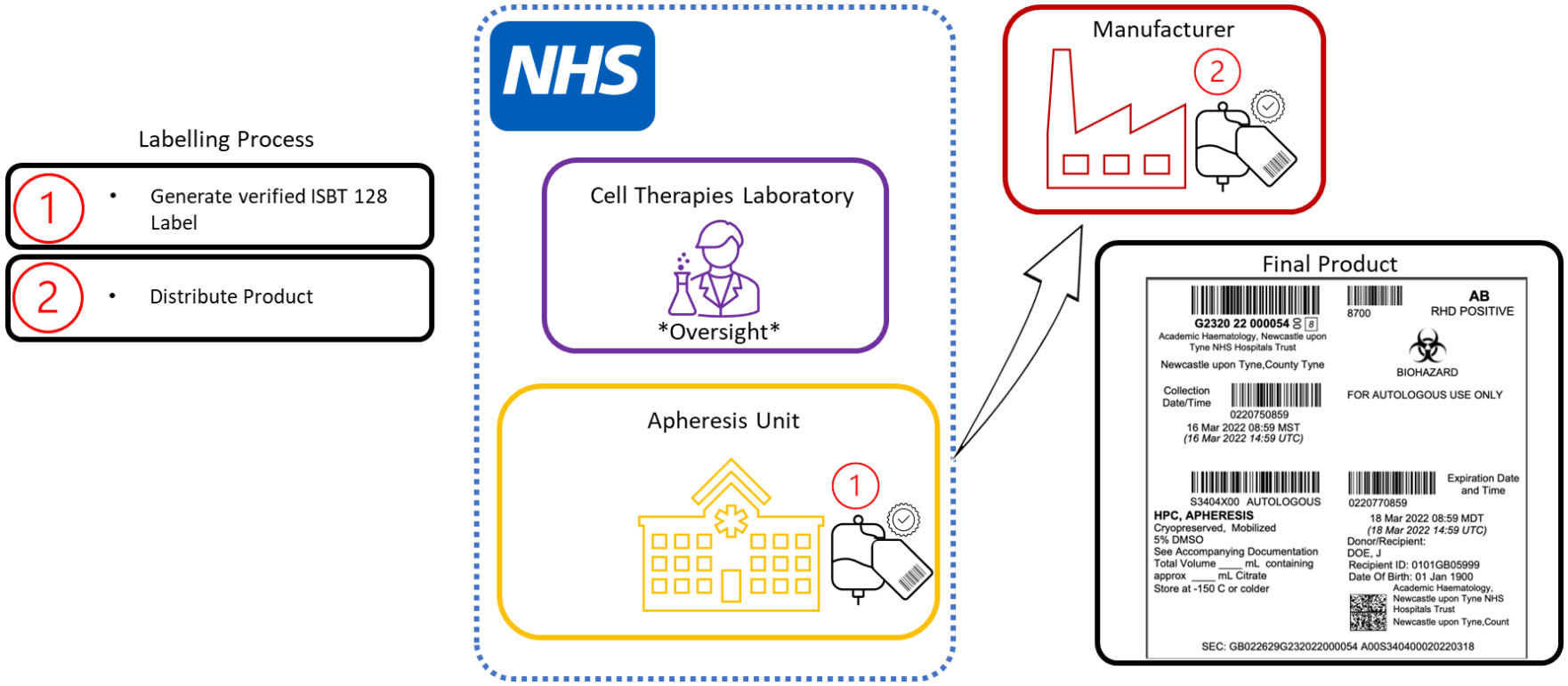

Figure 2. Updated ISBT 128 Compliant Practice at NUTH

The updated process enables the production of labels in line with JACIE v.7 utilising the STAFA labelling solution provided by Terumo BCT. All labels are produced at the bedside with automated generation of Donor Identification Number, Single European Code and other identifiers. This has reduced the burden on staff whilst allowing full verification of label information and traceability throughout the process.

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Design and Methods

A working group of NUTH and CGT Catapult representatives was established to deliver this project. The group identified potential suppliers of apheresis product labelling solutions, the process for implementing any chosen solution and associated governance approvals required.

Following this, the below processes for implementation and approvals were identified:

Implementation & approvals process

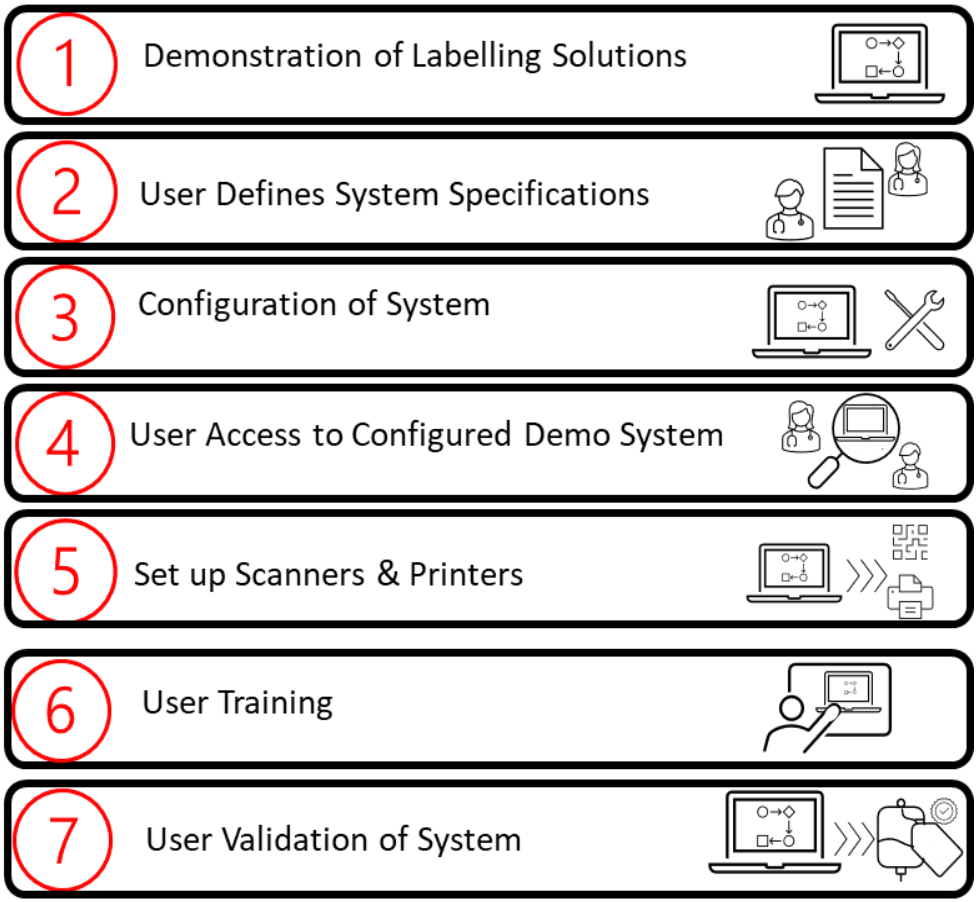

Figure 3. Process for Implementing the New Labelling System

The implementation of the system required the procurement, specification design, configuration, and installation of the chosen system. After which, staff training was required to ensure full functionality and the ongoing use of the system.

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Running parallel to the implementation, a series of site-led approvals were required to ensure the updated labelled process was compliant with information governance regulations. This required liaising with site-led organisations such as the Digital Design Committee (DDC) and key individuals such as the Data Protection Officer (DPO) and Change Manager.

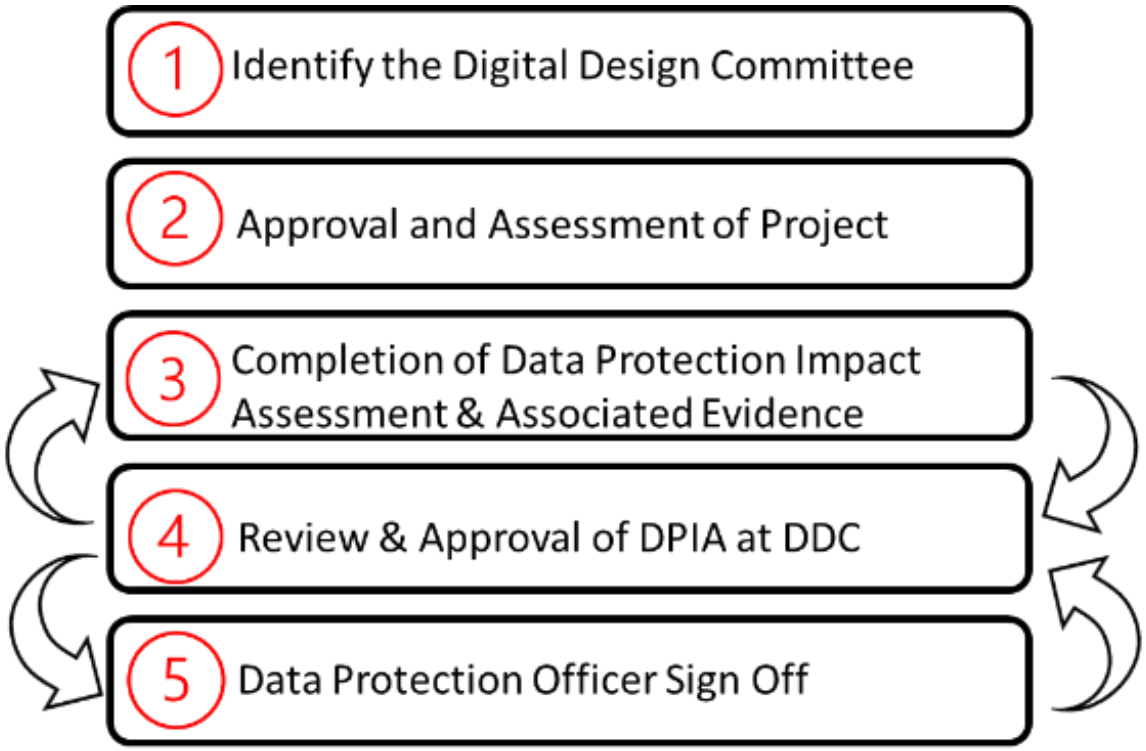

Figure 4. Governance Approval Process at NUTH

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Learning Points

The key challenges experienced during implementation of the labelling solution, and an examination of the causes and lessons learned from them included:

Learning Point 	Advice 
NHS Organisational Structure • NHS Trusts and Health Boards delivering advanced therapies generally have large and complex structures which can add complexity to the introduction of new systems and processes; an interdepartmental approach to achieve such introductions is generally required.	• Identify and engage all relevant NHS directorates, departments and key personnel including, for example, in: ○ Apheresis Unit ○ Stem Cell Lab ○ Pharmacy ○ IT ○ Governance (such as Human Tissue Authority Designated Individual; Information Governance)
Advocacy & Accountability for Change • Effecting change is challenging in an environment where NHS services are under considerable pressure. Empowering NHS representatives that advocate for change and enabling them to be accountable for such a change, is vital. Such personnel need to raise and maintain the profile of the change required with NHS decision makers.	• Seek specialist subject matter expertise to help develop the business case for the new system and then support its implementation. Job roles such as the representative responsible for JACIE (being cross-functional), ATMP Pharmacist and HTA Designated Individual could be helpful in this process.
Sourcing Compatible Equipment • NHS Trusts and Health Boards are required to comply with national policies relating to the procurement of equipment and approval of suppliers; engagement with the appropriate procurement personnel for guidance at the earliest stage is therefore beneficial.	• Be aware of the Trust's / NHS Board's procurement policy before embarking on any digital infrastructure project. • Within the scope of this policy and process, liaise with IT departments to identify any previously approved suppliers that provide labelling equipment of similar specification.
NHS Governance Review (Data Protection Officer Approval) • Governance review and approval is critical to NHS digital infrastructure projects. The detailed technical requirements of ISBT 128 labelling can be a new and niche subject; a full understanding of the labelling process and the importance of ISBT 128 standards by key stakeholders (such as Digital	• Identify and upskill the appropriate people that can effect change in apheresis labelling within a Trust / Health Board. • Ensure the correct people and management/governance bodies are comfortable with the requirements of ISBT 128 to improve the efficiency of implementation. • Roles to identify:

Design Committees, NHS Data Protection Officers and change managers) is a prerequisite to gaining their approval for the introduction of a new system.	• Data Protection Officer • IT Team Member • Change Manager • Organisational bodies to identify: • Information Governance Committee • Change Management Board • Infrastructure Committee
Data Protection Impact Assessment (DPIA) • The completion of a Data Protection Impact Assessment (DPIA) is commonplace in NHS organisations. The completion, review and approval of this document is a collaborative effort between the relevant quality teams, NHS change managers, suppliers and the Data Protection Officer facilitated by the Digital Design Committee. The composition and format of any DPIA can vary across different organisations.	• Obtain a copy of the appropriate DPIA as early as possible • Review the content and requirements of the DPIA with the supplier before any formal submissions take place. • Have a full understanding of the review and approval process for such a document ahead of submission of any DPIA.
Staff Training • NHS capacity constraints can be a barrier to effect change when an investment of time for staff training is required to adopt a new system or process. • The 'train the trainer' approach proved to be an effective tool to cascade training on the STAFA labelling system.	• Include staff training as part of the implementation plan. Consider using a 'train the trainer' methodology to equip staff to use the new system and link to their Continued Professional Development to gain better engagement. • Arrange for teacher and refresher sessions to be delivered by the supplier to ensure staff become and remain competent.

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Appendix

ISBT 128 Compliant Label of Apheresis Collection for Sponsor Cellular Therapy Manufacture

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