



Procurement Non-Label Data Point Capture and Time Stamps



Background: In the UK at present there are a small number of licensed Advanced Therapy Medicinal Products (ATMPs) being administered as standard of care across the NHS. Throughout the procurement of cells or tissues as starting material for these ATMPs there is a high volume of data produced describing the procurement process. The extent to which this data is generated, recorded, and utilised by the NHS or manufacturers varies greatly. Accommodating this variability is costly to the NHS. The Advanced Therapy Treatment Centres (ATTC) Industry Advisory Group (IAG) Procurement & Labelling Working Group has set out to address this issue by workshopping a minimum data set required during an exemplar apheresis procedure.

Methods:

1. Set up a short-lived sub-group to examine data generated from the exemplar apheresis process.
2. Produce an exhaustive list of data produced.
3. Discussed, justify, and stratify data proposed data points as either:
 - i) **INDUSTRY: Procurement Data Point** – Data generated by the NHS during procurement of cells or tissues required by / submitted to ATMP manufacturers.
 - ii) **NHS Site: Procurement Data Point** – Data generated by the NHS during procurement of cell or tissues but **NOT** required by ATMP manufacturers.
 - iii) **Out of Scope**

Objectives:

- Produce a list of data points generated during the procurement of cells or tissues for ATMP manufacture.
- Demonstrate a schedule of data point generation and transfer.
- Demonstrate the importance of any data points to the relevant parties.

Definitions:

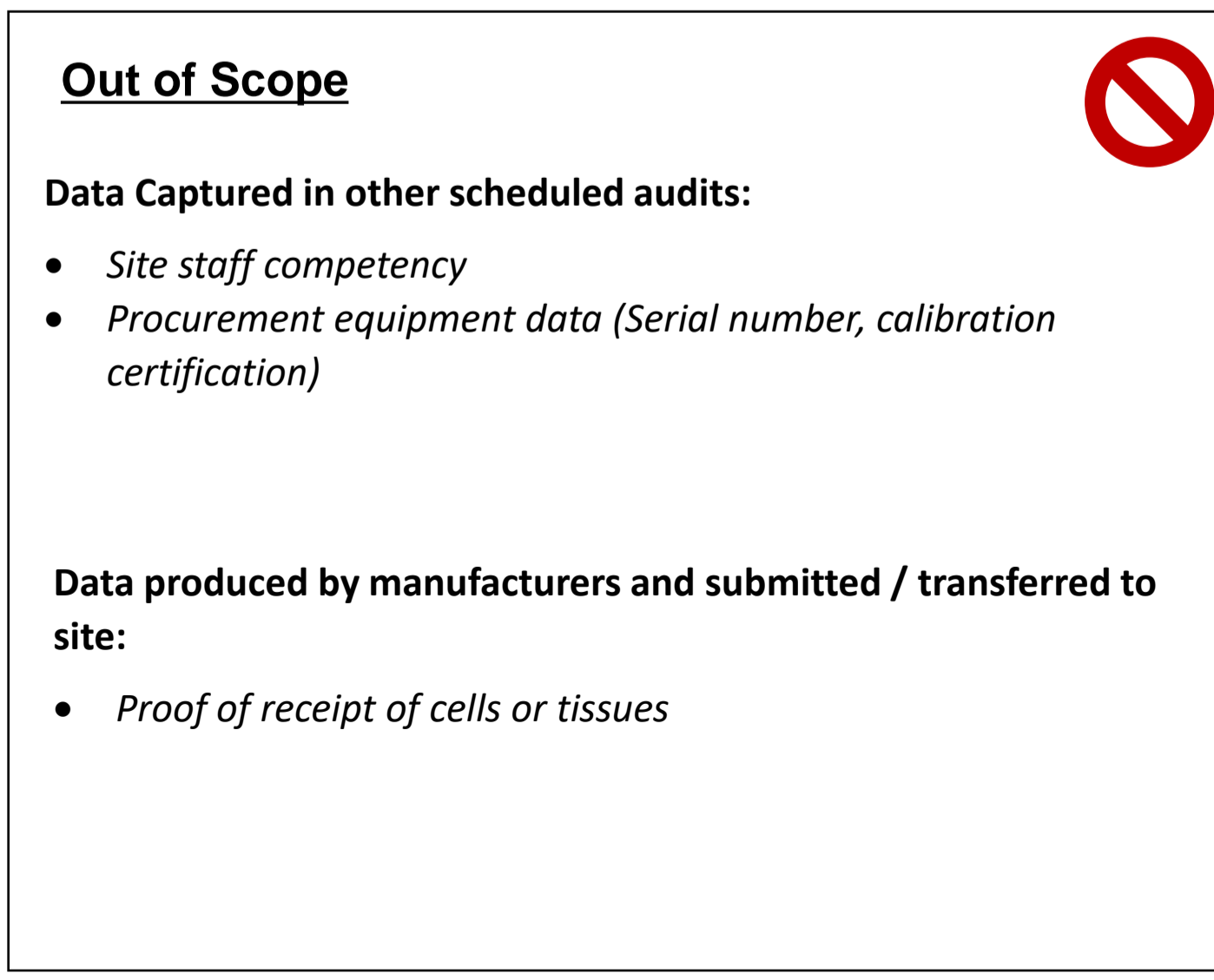
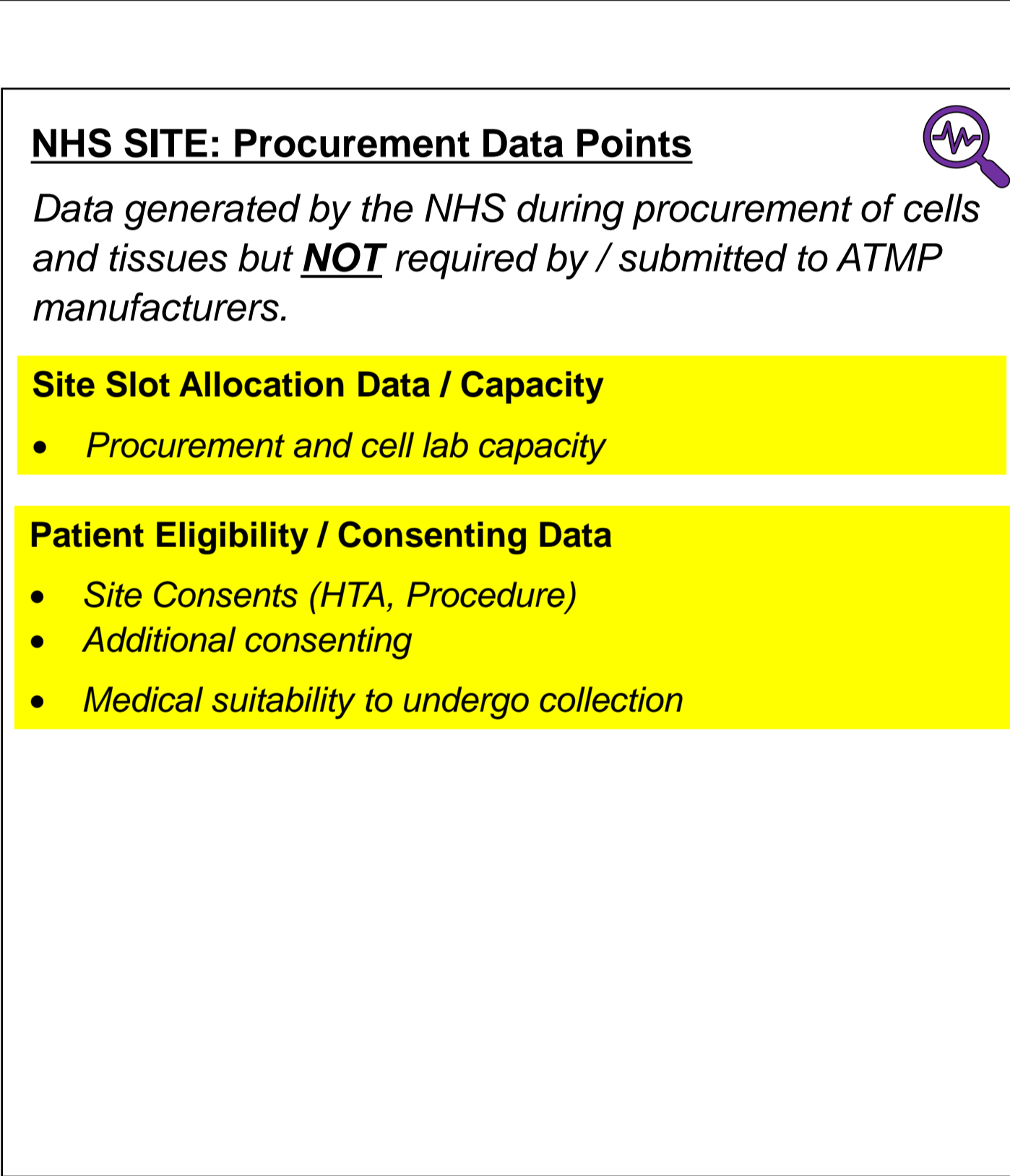
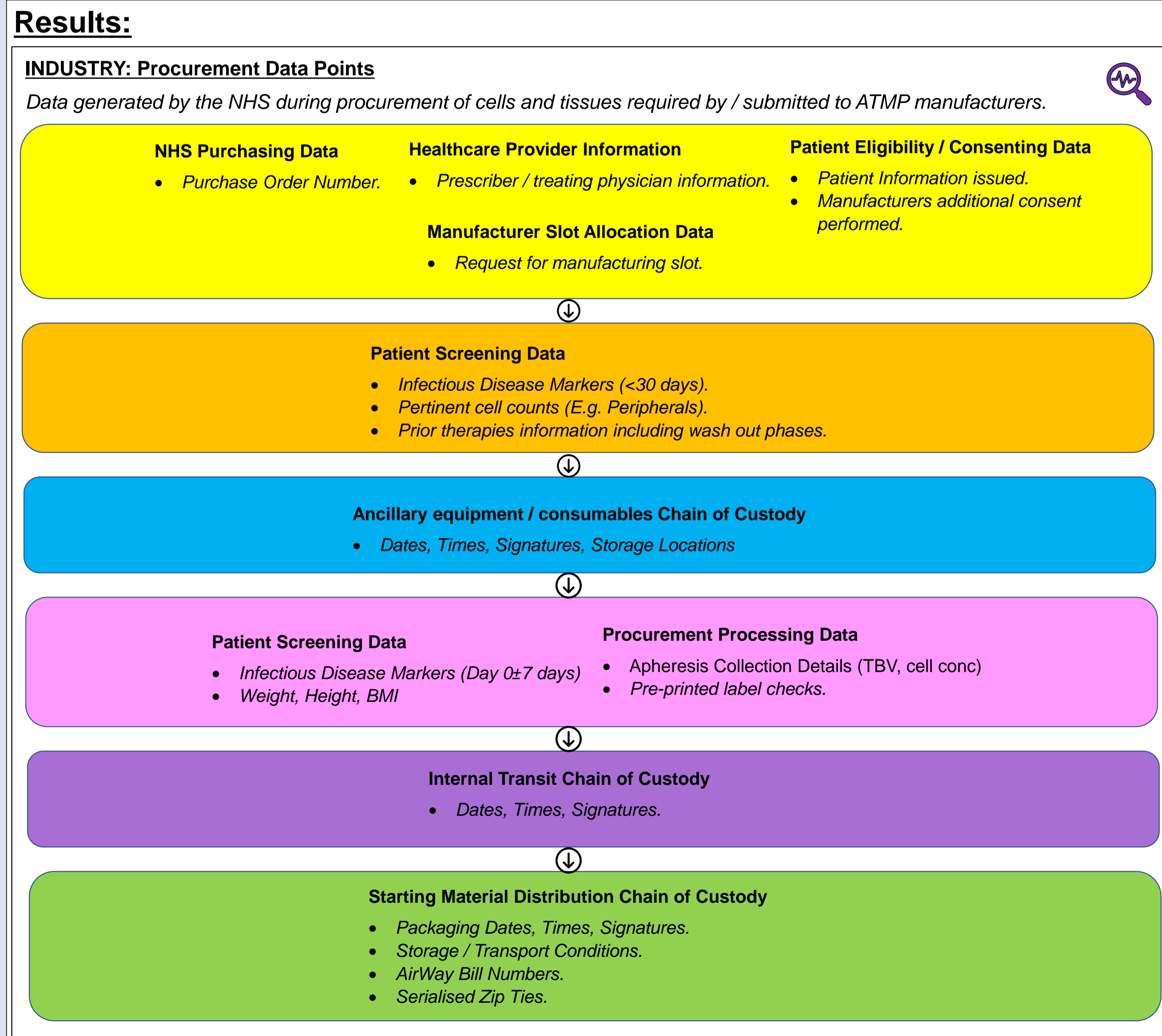
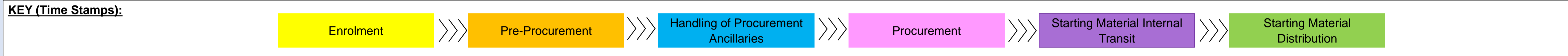
Procurement: The procurement of cell or tissues beginning at patient consenting through to distribution to manufacturer.

Non-Label: Data produced during a procurement process that does not appear on the procurement product label.

Data-Point: Information produced during the procurement process that:

- I) Is required by ATMP manufacturers for the manufacture process.
- II) Is **NOT** captured through scheduled auditing.

Time Stamp: Time at which NHS site representatives need to input / transfer data to manufacturers.



Discussion:

ATMP starting material procurements can be performed by a variety of methods for a variety of cells or tissues, making quantifying relevant data points difficult. The sub-group decided, to enable the most valuable outcomes, the exercise would need to be performed on an exemplar apheresis of fresh leukapheresis product for manufacture.

The limiting of scope in the exercise has affected the results however, the exercise has demonstrated the ability of manufacturers to come to a consensus on some elements of data transfer. To improve outcomes this exercise would need to be performed across more manufacturers and procurement processes including procurements requiring cellular processing (E.g. Cryopreservation).

The data mapping exercise yielded a high number of non-label data points pertinent to both the NHS and manufacturers. However, the reason for these data points importance to each party did vary. This led to some of disagreement over how to stratify some data points, this was resolved in the justification stage.

As greater numbers of ATMPs achieve market authorisation and are implemented at NHS sites, the number of procurement processes will increase. Without consensus agreement on standardised production and transfer of data the onerous resource burden for the NHS will increase.

Recommendations:

- 1) There is a system need for standardisation of data required by manufacturers for their manufacture process.
- 2) There is a system requirement for a standard reschedule for the request of data from the National Health Service' or other provider procurement sites.
- 3) When designing any cell orchestration platform manufacturers and developers should give equal importance to:
 - a. The product license requirements.
 - b. The ability for the National Health Service' to easily provide the data.
 - c. Time of data entry should be mapped closely to the operational needs of the department.

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