Quality Assurance & Technical Services Symposium 2025

Is Technical Services equipped for future clinical demands ? mRNA Cancer Immunotherapies

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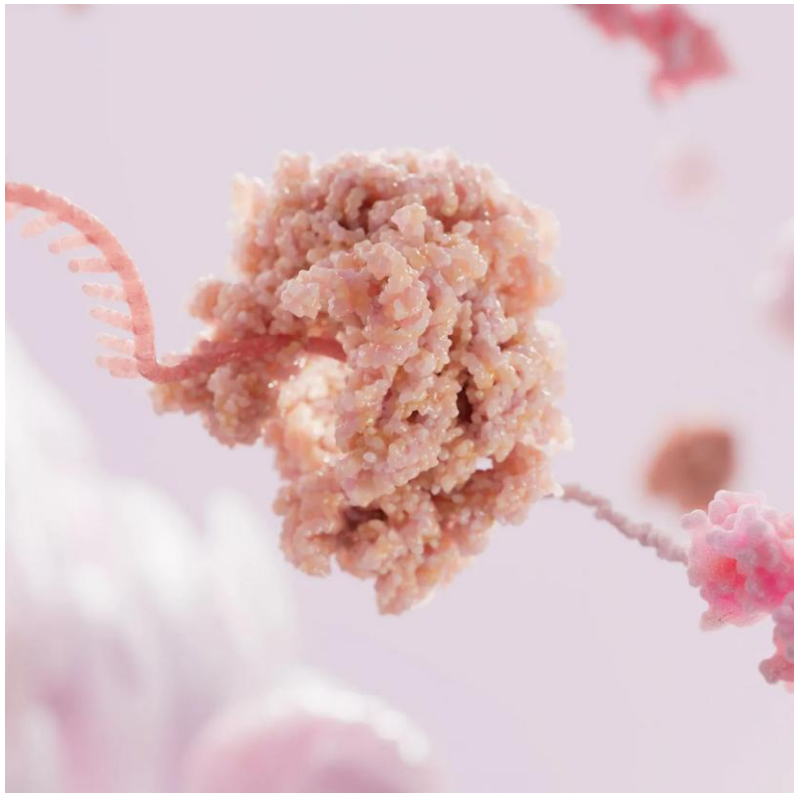
mRNA Cancer Immunotherapies – A Brief Overview

mRNA - A versatile drug class

What Is It?

- Messenger RNA (mRNA) is a single-stranded nucleic acid that instructs cells to produce specific proteins
- Delivered via lipid nanoparticles
- Synthetic mRNA does not integrate into DNA



In Cancer Immunotherapy, it aims to:

- Encode tumour-specific antigens or neoantigens
- Stimulates T-cell mediated immune responses against cancer cells
- In Personalised products it enables treatment, tailored to tumour profiles

Key Advantages:

- Transient, Non-integrating expression
- Rapid design and scalable manufacturing
- Suitable for both individualised and off-the-shelf therapies

mRNA Cancer Immunotherapies - Challenges for Technical Services

Storage and Stability:

Ultra-Cold Storage:

Requires storage at **-20°C to -80°C** to maintain stability.
Fragility of mRNA makes it prone to autohydrolysis and **rapid degradation**.
Strict temperature control is essential; even minor fluctuations can compromise efficacy and safety.

Limited Room-Temperature Stability:

Some mRNA products may degrade quickly at ambient conditions, necessitating cold-chain logistics and ultra-low temperature freezers.

Preparation Requirements:

Just-in-Time Preparation (Individualised products):

Due to **limited post-thaw stability**, preparation must align closely with administration schedules.
Short **shelf-life post-thaw** (often hours) demands precise coordination with clinical teams.

Countertop Preparation Feasibility:

If classified as non-hazardous and simple to prepare, could potentially be prepared directly in clinical ward settings using Aseptic Non-Touch Technique (ANTT), thereby reducing bottlenecks.

Manufacturing & Scalability:

Manufacturing Complexity:

Producing high-quality mRNA at scale is **challenging**, **requiring stringent control over purity, stability & consistency**.

Cost Considerations:

While mRNA therapies are cost-effective compared to biologics, the **high-cost** of lipid nanoparticles (LNPs), ultra-cold storage, and advanced manufacturing remains a barrier.

Workforce & Training:

Familiarity with mRNA Therapies: Some NHS sites may be in the early stages of developing the expertise required to handle, prepare, and administer mRNA therapies, which have distinct requirements compared to traditional medicines.

Complex Preparation Protocols: The preparation and handling of mRNA products, such as thawing, maintaining sterility, and adhering to time-sensitive workflows, demand specialised skills and knowledge.

Regulatory and Compliance:

Compliance with regulatory standards for novel mRNA therapies is evolving. Ensuring adherence to these standards while fostering innovation can be challenging.

mRNA Cancer Immunotherapies – Implications for NHS Technical Services

NHS technical services are key to delivering priority oncology therapies safely

Storage & Logistics:

Infrastructure – facilities/capacity upgrades: (-20°C /-80°C Freezers, Physical Space, Uninterruptible power source)

Cold chain control: real-time temperature monitoring. Robust and validated shippers/Temp for transport.

Formulation:

Local risk assessment for the preparation area, low risk, non-hazardous products could be prepared outside of aseptics, in a clinical setting using ANTT.

Ensure all staff handling IMP (i.e., prep and admin) are educated on the time-sensitivity for administration.

Scheduling & Workflow:

Just-in-time preparation demands precise co-ordination with clinical teams

Tight scheduling to align with patient-specific dosing windows

Robust communication between clinical and pharmacy staff to schedule patients per aseptic capacity.

Traceability:

Individualised dosing requires enhanced chain of custody

Secure transport & handover protocols and cross-checks to ensure Right patient, Right Dose.

Digital Integration & Upskilling:

Digital integration for scheduling, traceability, preparation & administration

Upskilling staff for oversight and handling of novel therapies – knowing the internal committees, setup processes

Estate & Facilities:

Assessment of suitability of existing estate and facilities

May require upgrades, new facilities, or additional space, in line with the NHS 10-year Health plan

mRNA Cancer Immunotherapies – Countertop Preparation in Clinical Areas

A Decentralised Preparation Model for products that are non-hazardous and simple to prepare.

Advantages

Builds on COVID-19 workflows for mRNA medicines

Enables on-site, just-in-time preparation near the point of care

Reduces reliance on pharmacy aseptic units

Key Roles for Pharmacy Technical Services

Cold chain oversight:	Managing storage, thawing, and expiry tracking
IMP accountability:	Ensuring correct product, patient, and protocol alignment
Training & SOP development:	Supporting clinical teams with validated procedures and policies
Governance & audit:	Supporting audit readiness, and regulatory compliance
Sponsor expectations:	Pharmacy services are ideally placed to maintain standards for IMP handling
Risk assessment:	Evaluating the most appropriate preparation location, especially relevant for low-risk products

mRNA Cancer Immunotherapies - Regulation

Individualised mRNA immunotherapies are currently classified as Advanced Therapy Medicinal Products (ATMPs) under MHRA guidance.

Unlike cell therapies and some gene therapies (though regulatory classification may vary), mRNA products:

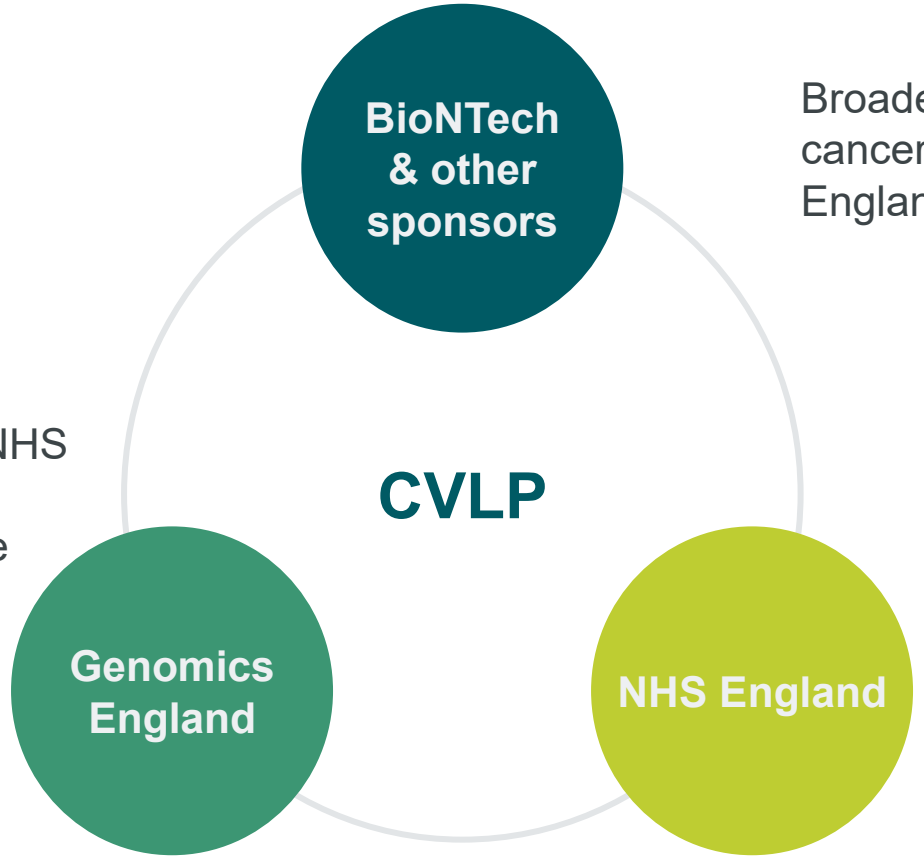
- Don’t involve living cells
- Are synthetically manufactured
- Share certain features with conventional biologics (i.e., synthetic manufacturing, non-cell based), but also present distinct considerations

This could lead to overburden some risk mitigations compared to other similar technologies.

The outcome of the MHRA’s *Guideline on individualised mRNA cancer immunotherapies* may offer scope for reclassification or streamlined pathways.

mRNA Cancer Immunotherapies - Collaboration

Cancer Vaccine Launch Pad (CVLP) – NHS England-Led Initiative



Broaden access to mRNA cancer ‘vaccine’ trials across England

Rapid identification of eligible NHS patients for trials:
patient-to-trial matching service

Shared goal to provide up to 10,000 NHS patients with BioNTech’s individualised mRNA immunotherapies by 2030

BioNTech participates in CVLP in collaboration with NHS England and Genomics England.

mRNA Cancer Immunotherapies - NHS 10 Year Health Plan for England

How might mRNA immunotherapies fit into the “3 big shifts” in the NHS 10 Year Health Plan ?

From Hospital to Community:

Clinical Trials: mRNA immunotherapy candidates may be prepared and administered in outpatient or community settings.

Licensed Products: Future mRNA therapies could potentially be delivered in primary care, requiring pharmacy services to support decentralised models.

Assess estate readiness and support governance in settings outside hospitals

From Treatment to Prevention:

Clinical Trials: mRNA immunotherapy candidates are being trialled as therapeutic immunotherapies, targeting early-stage or high-risk patients.

Licensed Products: May be used with the aim of preventing recurrence or progression, shifting focus from reactive treatment to proactive care.

Adapt to support broader patient cohorts and indications.

From Analogue to Digital:

Clinical Trials: mRNA IMPs require robust and agile digital systems for trial management, traceability and temperature monitoring.

Licensed Products: Integration with digital platforms for adherence tracking and pharmacovigilance.

Embrace digital infrastructure to meet sponsor and regulatory expectations.

The NHS 10-Year Health Plan envisions clinical trials as part of routine care with a focus on personalised medicine, genomics, and digital integration.

NHS 10 Year Health Plan for England: https://assets.publishing.service.gov.uk/media/6888a0b1a11f859994409147/fit-for-the-future-10-year-health-plan-for-england.pdf
* not specific to BioNTech mRNA immunotherapies

Thank you for listening, any questions ?