Decentralised and Point of Care manufacturing - a UK perspective

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28th June 2023

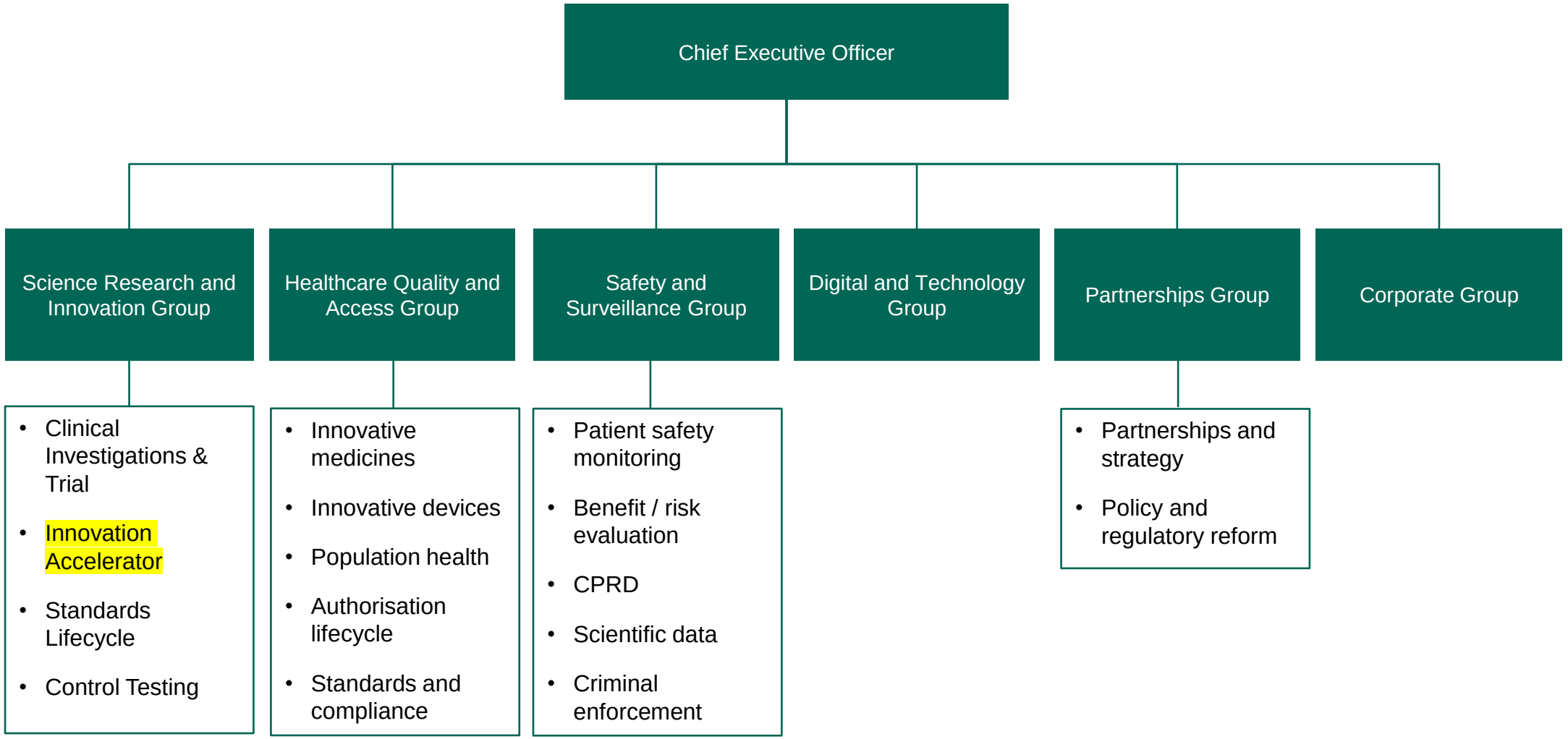
Disclaimer

The views expressed are those of the presenter and not necessarily those of MHRA.

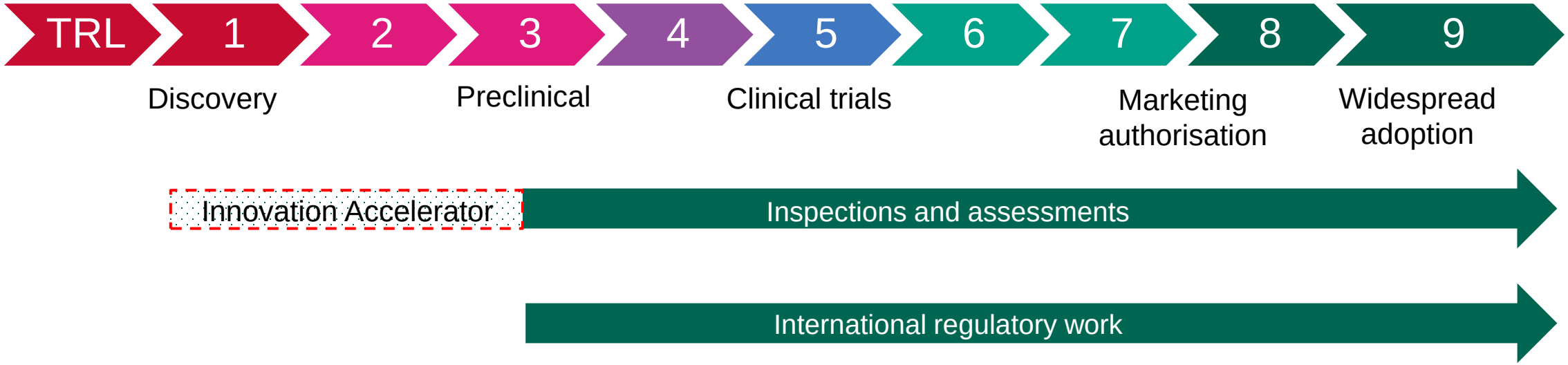
Agenda

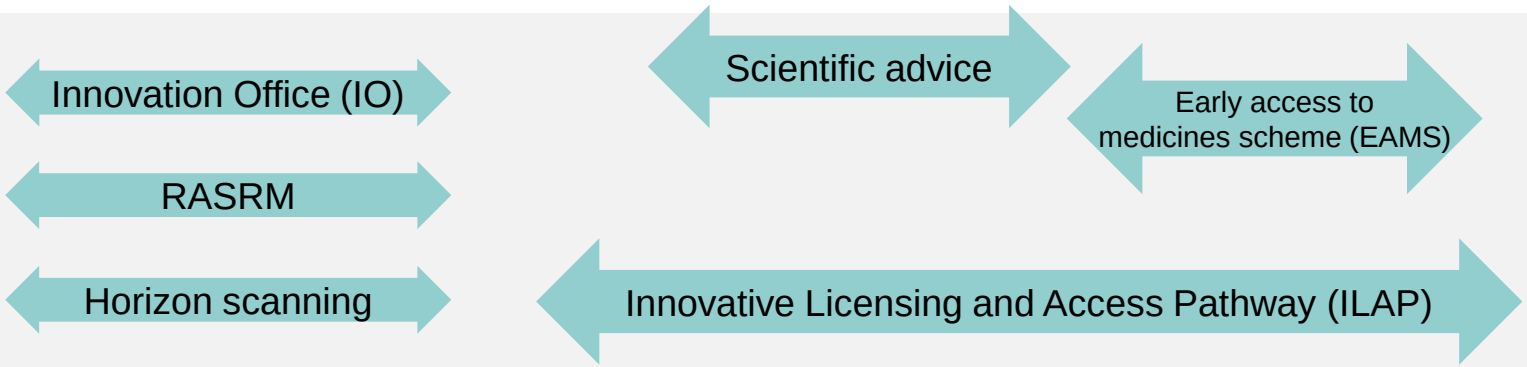
- Structure and support for innovation at MHRA
- Innovation – regulatory changes
- DM / POC framework

MHRA organisation structure

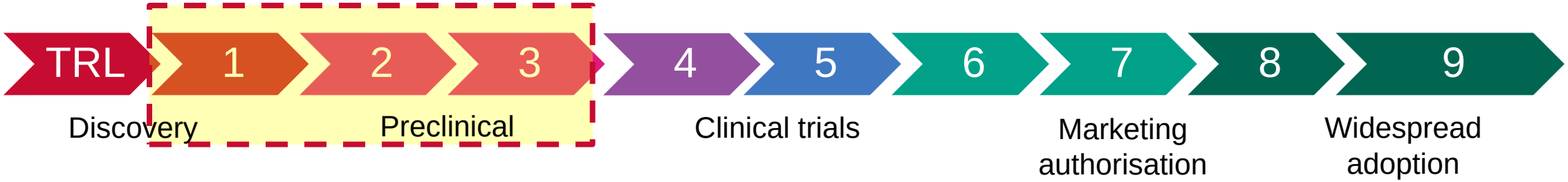


Innovation – support across the lifecycle





Innovation Office / RASRM



- Established in 2013, includes the Regulatory Advice Service for Regenerative Medicines (RASRM) established in 2014
- Provides free and confidential regulatory information, advice and guidance to academics, not for profit organisations, patient groups involved in research and industry whether based nationally or internationally
- Receives enquiries on innovative developments:
  - in medicines, medical devices and blood for transfusion
  - using new or novel technology, materials, methods or approaches or manufacturing processes
- Triage process - assess enquiries to determine action/s
- Part of engagement sequence during translation process to Clinical Trial Application (CTA), Marketing Authorisation Application (MAA) and to GXPs including GMP for manufacturing authorisation application

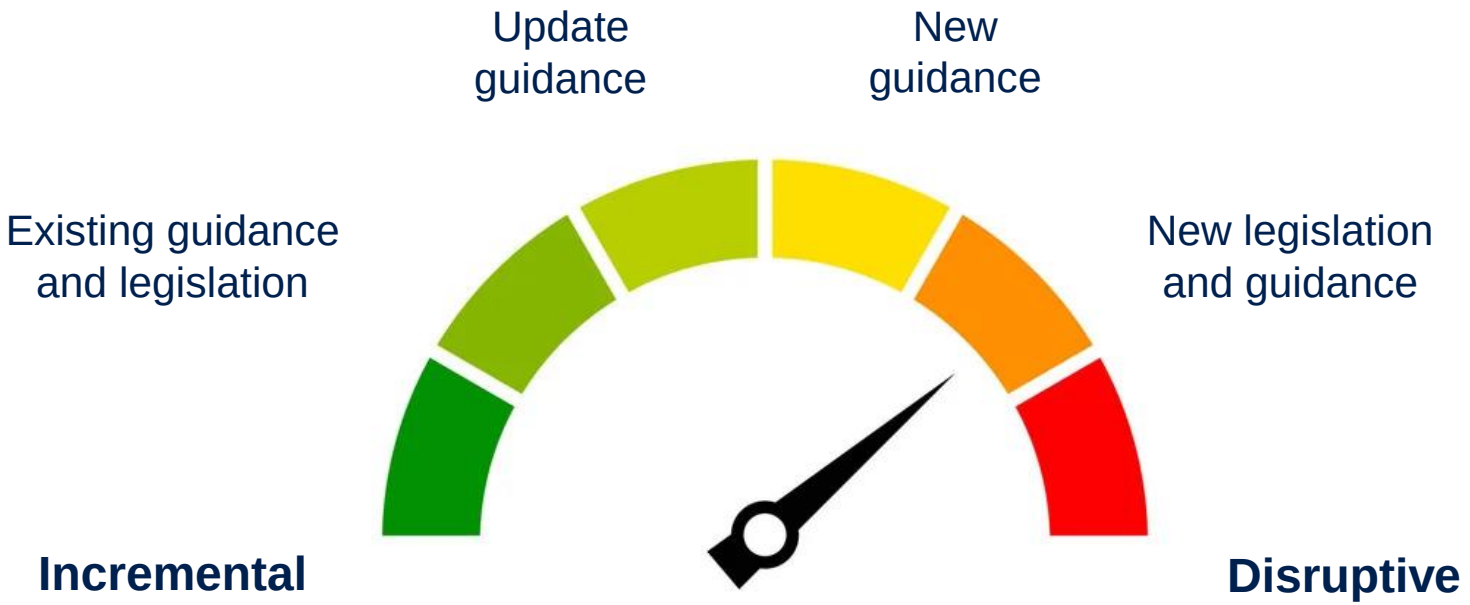
Horizon scanning

Types:

- Primary: derived from searches, from other government departments, from advisory bodies
- ‘Applied’: derived from engagement activities, from IO enquiries and scientific advice meetings (SAM)

Regulatory actions - will depend on a range of factors that may identify an Actionable Horizon Scanning Signal which will result in a regulatory change

Innovation - degrees of change / regulatory change



- UK already have powers to make guidance changes
- Medicines and Medical Devices Act (Feb 2021) gave powers to make legislative changes

Disruptive change – Distributed / Point of Care manufacture

Objectives of the new framework

Develop regulation (i.e. legislation and guidance) that:

- Supports a broadened range of manufacturing and supply options for patients to access new treatments
- Has control measures equivalent to those currently in place to ensure that DM and POC products have appropriate QSE properties
- Accommodates future developments

DM/POC manufacture - key features

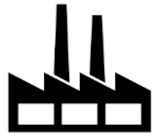
- POC - short shelf life of starting materials or finished products
- Large number of manufacturing sites
- Intermittent nature of manufacture
- Novel and wide range of manufacturing locations
- Applicable to a wide range of dosage forms:
  - medical gasses
  - biological/biotech/blood
  - small molecule
  - advanced therapy medicinal products (ATMP)

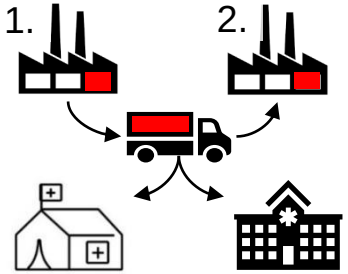
Changing spectrum of manufacturing activities

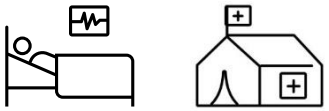
Mass market
Global

Personalised
Local

Factory | **Modular** | **Mobile** | **POC** | **Home**







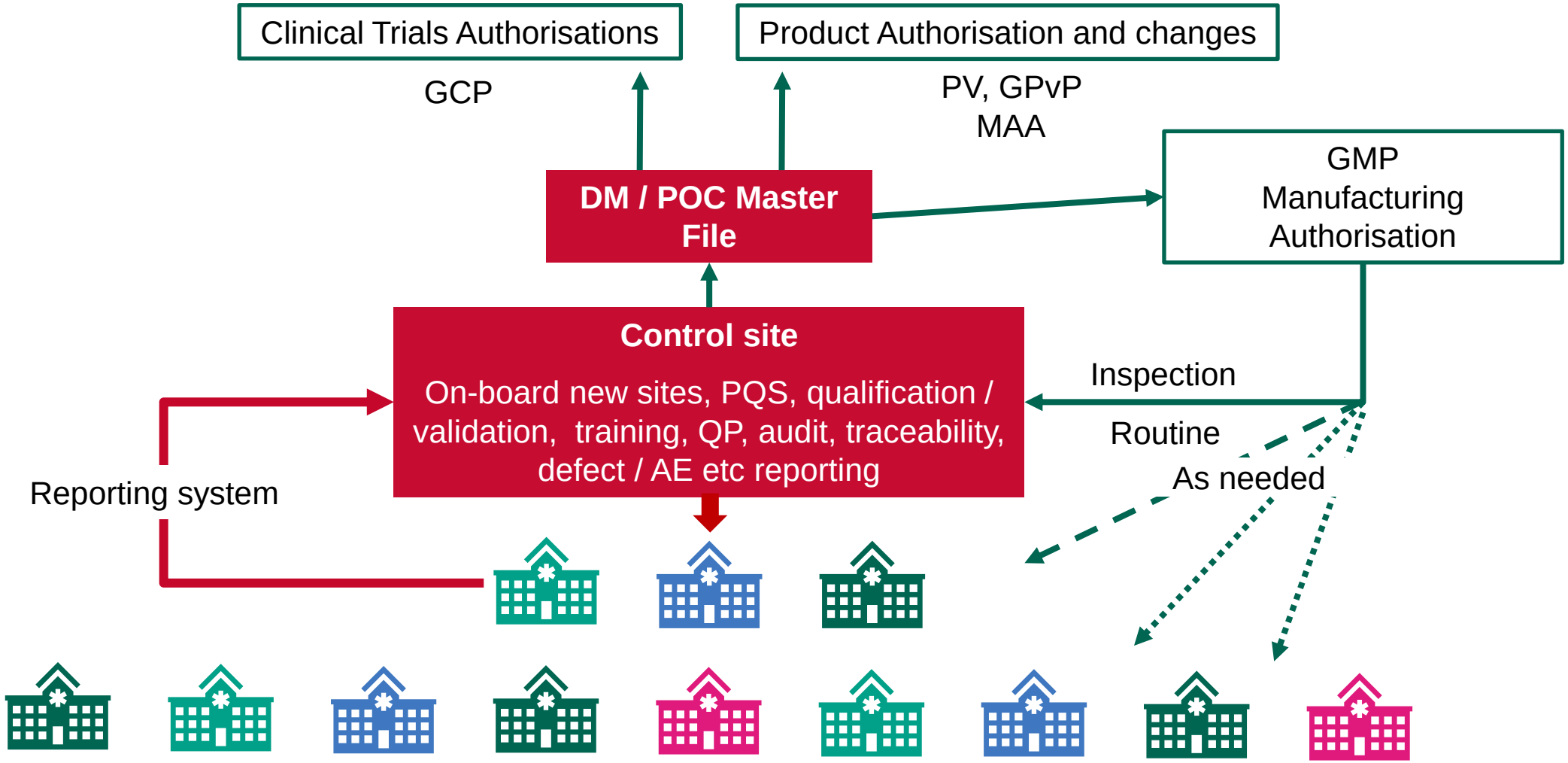
Large scale
Stable batches
Small number of manufacturing sites

Single person ‘batch’
Short shelf life
Large number manufacturing sites

Centralised manufacture

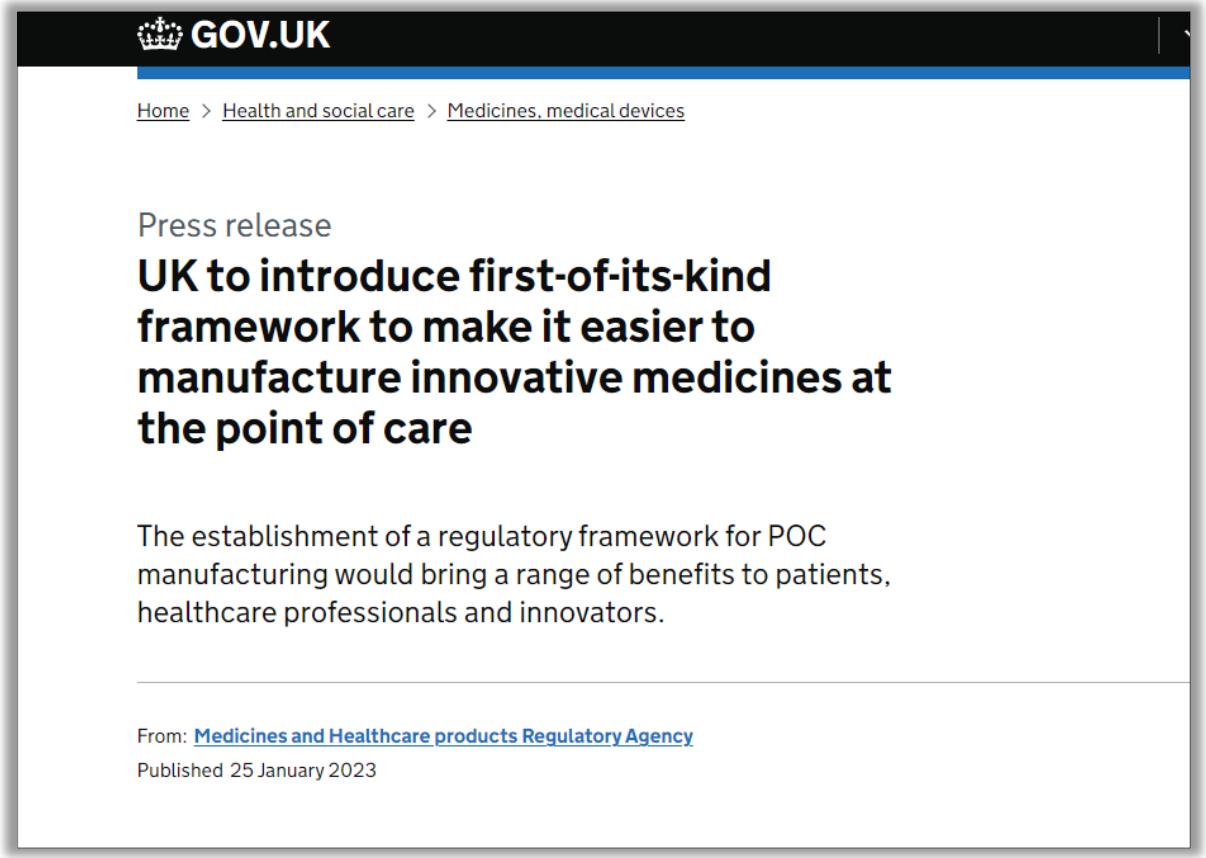
Decentralised / distributed manufacture

Control site and Master File



Public consultation

- Six week consultation, closed 23rd September 2021
- 600 visits to consultation site, >50 completed responses received
- Respondents:
  - 67% individuals | 33% organisations
  - 80% UK | 20% international
- Government response published on 25th Jan 2023



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Press release

UK to introduce first-of-its-kind framework to make it easier to manufacture innovative medicines at the point of care

The establishment of a regulatory framework for POC manufacturing would bring a range of benefits to patients, healthcare professionals and innovators.

From: Medicines and Healthcare products Regulatory Agency

Published 25 January 2023

Public consultation – questions and outcomes

1. **Do you agree that point of care manufacturing is sufficiently different to the current ‘standard model’ of factory-based manufacture of medicinal products that a new framework is required?**
   - Very significant support for the need for a new framework
   - Manufacture at POC is sufficiently different from the current centralised model of manufacture
   - Ensure appropriate controls present, staff training, oversight by robust reporting systems, clarity on alignment and avoidance of overlaps with current exemptions

2. **Do you agree with the proposals for a new regulatory regime for POC products?**
   - Very significant support for the proposed framework based on hub and spoke model and POC Master File
   - Balance requirements for product Quality, Safety and Efficacy whilst avoiding excessive requirements that might hinder patient access

Public consultation – questions and outcomes (continued)

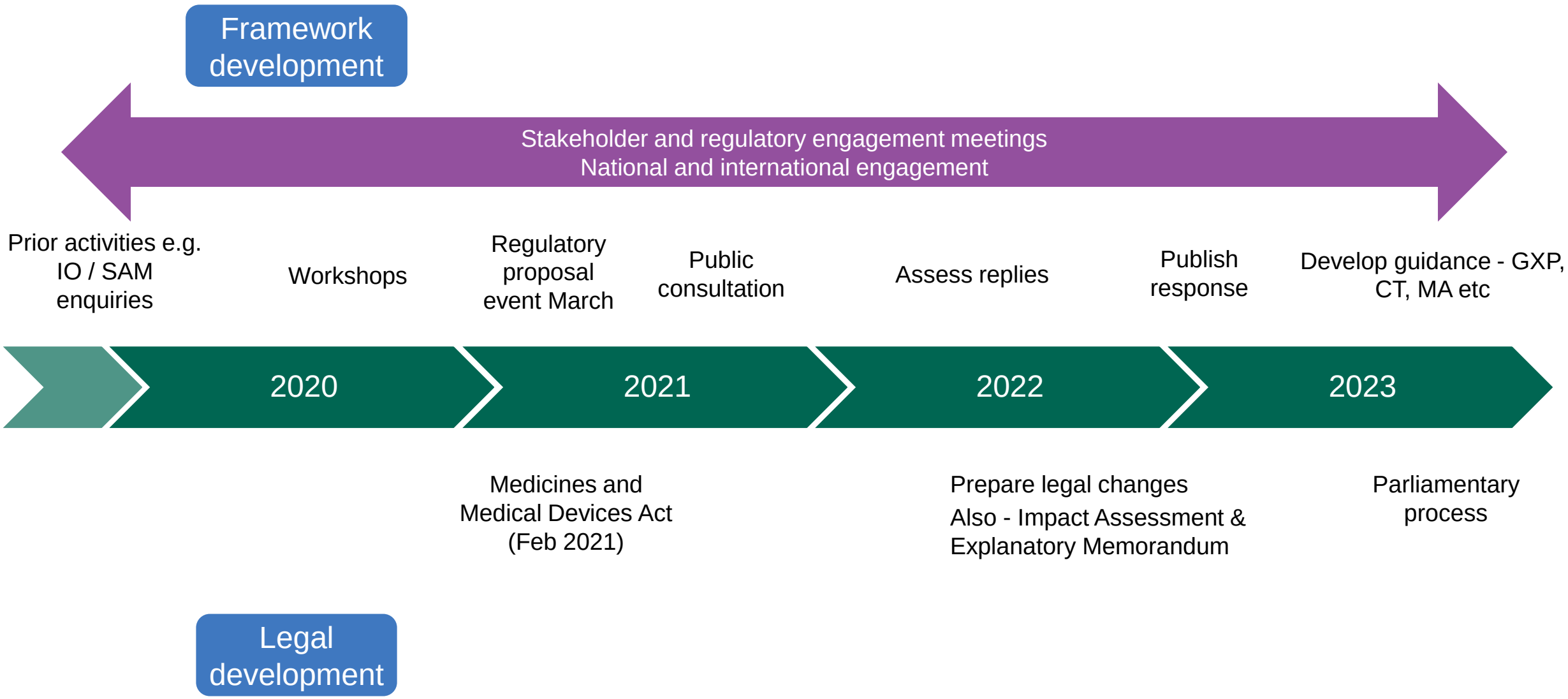
3. **We are seeking to clarify the scope of the new POC regulatory framework in relation to the above manufacturing categories *[3a. modular manufacturing, 3b. home-based manufacturing, 3c. other areas, 3d. other controls]***
   - Very significant support for broadening the range of manufacturing options to include modular manufacture and home-based manufacture

4. **Are there other aspects of the POC framework that you believe have not been considered? This could include any additional positive and negative impact that the framework may have on the delivery of healthcare in the UK.**
   - Good governance and controls at POC sites
   - Need an enabling framework to allow for future developments
   - Avoid any undermining current ‘standard model’ of manufacture
   - Continue engagement with stakeholders

Next steps

- Outcomes have informed legal changes, Impact Assessment and development of regulatory guidance texts
- Legal changes - to the Human Medicines Regulations and the Clinical Trials Regulations
  - Builds on existing legislation with adaptions and controls to ensure appropriate product QSE in a proportionate and tailored framework
  - Creates e.g. Control Site, definitions
  - Amend e.g. Master File – DM MF / POC MF, PV obligations
  - Disapply e.g. requirement to name all sites of manufacture, Qualified Person (QP) at each site
- Development of operational and regulatory guidance texts started
- Continue engagement with international regulatory agencies and national agencies

Project overview



Many thanks for your attention.