

Preparing early for future biosimilars

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The first stop for professional medicines advice

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Why plan early?

- Extend the planning window
- Product, price and framework details may be confirmed relatively late
- Much of the groundwork does not depend on knowing the eventual brand
- Many of the activities that consume the most resource are largely independent of which manufacturer ultimately wins the contract.
- Increase capacity to manage within current resource
- Early readiness allows mobilisation when the commercial position becomes clearer

Horizon scanning to identify opportunity

- Loss of Exclusivity
- Biosimilars in pipeline, clinical development, or regulatory assessment
- Indicative planning window
- Key uncertainties and dependencies
- Updates as position changes

*****Prescribing Outlook 2026: LoE and Biosimilar Pipeline Reports*****

Future biosimilars

- Vedolizumab
- Pertuzumab
- Trastuzumab SC
- Romiplostim
- Abatacept
- Certolizumab
- Ocrelizumab

FY 27/28 & 28/29

Where there is not a biosimilar established already

Key uncertainties and dependencies

Uncertainties

- If LoE will be delayed
- Exact launch timing
- Framework outcomes
- Final acquisition costs
- Product presentations and devices
- Homecare arrangements

Dependencies

- MHRA approval
- NHS framework award
- Intellectual property and patent litigation outcomes
- Availability and supply

Intellectual Property & Litigation

Timings and outcomes are uncertain and may delay or accelerate biosimilar market entry



Estimated LOE

- Loss of exclusivity
- Can be estimated years in advance



Challenge or Infringement

- Biosimilar company may challenge patent validity or scope
- Originator company may allege infringement of IP rights



High Court Proceedings

- Evidenced claim issued.
- Exchange, expert evidence and hearings.



Judgement

- Court decision on patent validity, infringement, or both.



Appeal

- Appeal may be lodged.
- Company not happy with the court decision



Settlement

- Parties may reach a settlement agreement.
- Originator company agrees to biosimilar launch



Market Entry

- Also dependent on:
- MAA,
- NHS contract,
- manufacturer lead time, and
- supply readiness.

Degree of certainty

Loss of exclusivity is often estimated years in advance, but the timing of actual market entry may not become clear until legal barriers are resolved. Visit our resources to learn about this: <https://sps.nhs.uk/articles/understanding-biosimilar-and-generic-market-entry/>

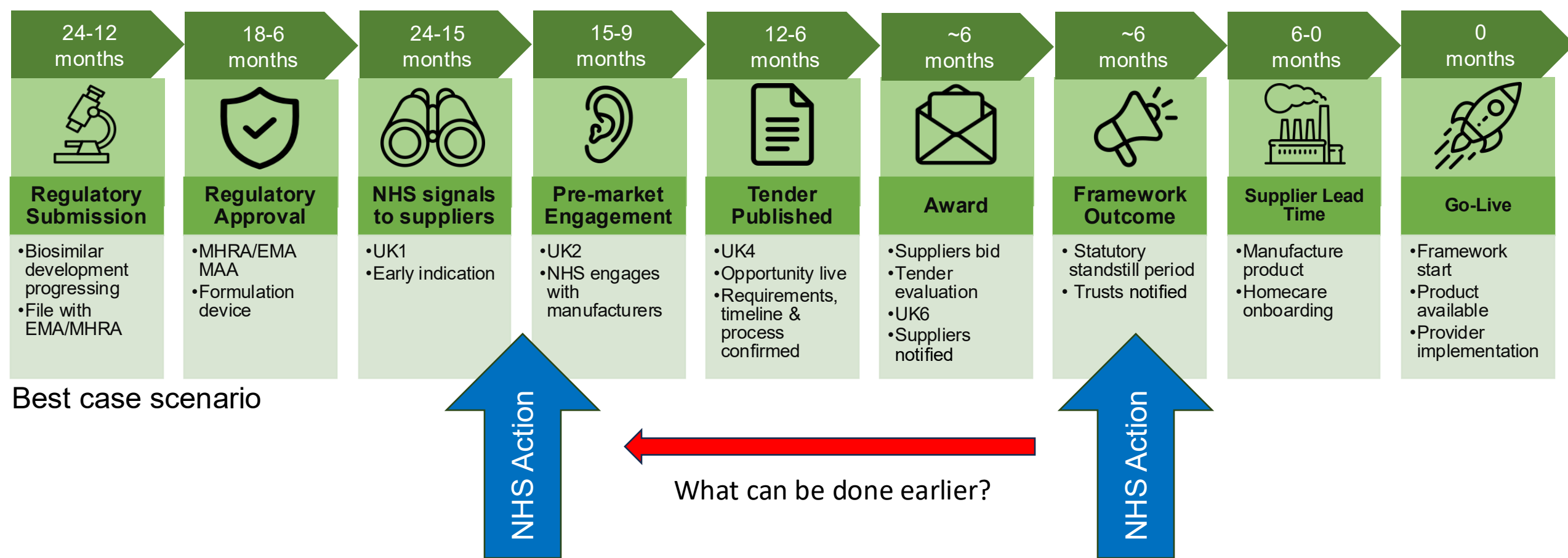
Do we need all the answers?

Known

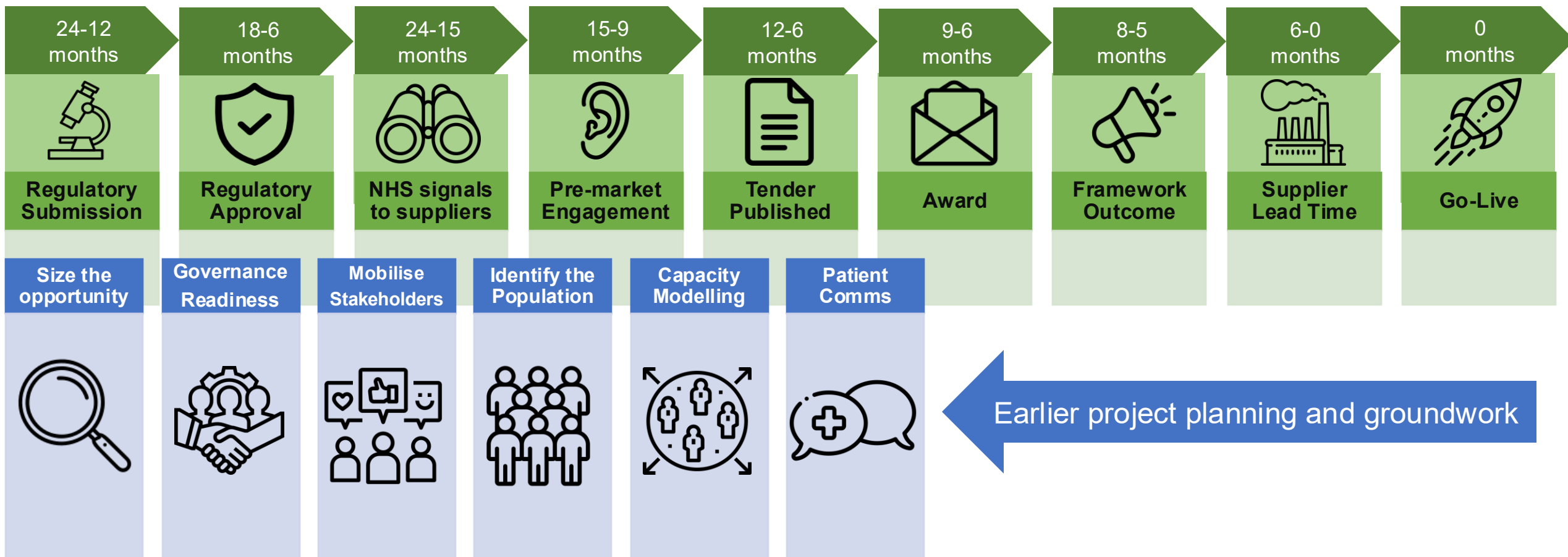
- LoE is approaching or occurred
- Biosimilars are in development
- NHSE Medicines Value and Access and SPS Procurement are planning
 - Engaging with manufacturers
 - Aligning NHS tenders contracts to likely product availability
- Intelligence will improve over time
- Significant NHS opportunity

What can start now?

Reverse roadmap



Reverse roadmap



Size the potential opportunity

- Establish current annual expenditure and activity
- Plausible discount/uptake scenarios from practice
 - Denosumab • Ustekinumab • Aflibercept • Natalizumab vials • Tocilizumab

Discount/uptake estimates can be based on national Define data and reflect the observed change in cost per unit over a two-year time horizon

- Planning scenarios: Model a range rather than a single figure
 - 25% discount • 50% discount • 75% discount
 - 60% uptake • 75% uptake • 90% uptake
- **Baseline annual expenditure x uptake x assumed discount**
- Refine estimates as pricing, uptake assumptions and implementation timelines become clearer
- **The scale of preparation should reflect the scale of the opportunity!**

Outputs:

- **Indicative value of the opportunity**
- **Decision on whether the opportunity justifies early planning**

Check governance readiness

- Is there an organisational biosimilar policy or position statement?
- Are decision-making and approval routes already defined?
- Is there an agreed principle for switching clinically appropriate patients?
- Is there an existing switch checklist or standard operating process?
- Are processes and tools available for:
 - patient information and consultation recording?
 - clinical exceptions?
 - escalation of concerns?
 - adverse event reporting and outcome monitoring?
- Which documents can be generic and prepared now?
- Which elements must wait for the selected product or device?

Outputs:

- **Governance gap analysis**
- **Action plan with named owners**

Mobilise stakeholders

- Make relevant teams aware that a biosimilar may become available
- Confirm switching is clinically acceptable in principle
- Identify concerns, barriers and support requirements
- Capture learning from previous switches
- Agree a plan:
 - Who will lead operational delivery?
 - Which teams need to be involved?
 - How decisions will be made?
- Identify dependencies
 - Blueteq
 - Electronic systems
 - Homecare service specification
 - Workforce training

Outputs:

- Stakeholder map
- Named clinical and operational leads
- Prioritised concerns and dependencies log
- Agreed actions and owners

Identify the population

➤ Agree data sources

- Homecare provider data
- HCD PLD dataset
- Prescribing or dispensing systems
- EPR and clinic lists

➤ Quantify

- Total patients
- Patients by indication or specialty
- New starters Vs Established patients
- Prescribing and supply frequency

➤ Stratify where possible and useful:

- appropriate for routine switch
- requires further clinical review
- potential clinical exception
- practical or device-support needs
- patient concerns already identified

Outputs:

- **Validated patient cohort**
- **Patient stratification and implementation approach**

Capacity modelling

- Calculate routine activity:
 - Prescriptions per month
 - Supplies per month
 - Clinic contacts
- Define additional tasks:
 - Record review
 - Patient communication
 - Clinic contacts
 - Prescribing activity

Aim to incorporate activity into routine care wherever feasible

- Quantify any residual capacity gap.
- Estimate time per task, multiply by quantity, and map over implementation period

**Number of patients × tasks per patient × time per task
÷ available implementation weeks
= weekly capacity requirement**

- Can the gap be managed?
 - Business as usual
 - Temporary backfill
 - Task delegation & skill-mix review
 - Phased implementation
 - Additional resource

Outputs:

- Weekly activity requirement
- Capacity gap
- Resourcing plan

Patient communication

- Socialise biosimilar concept in **routine patient interactions**

"Biosimilar versions of your medicine are expected to become available in the future.
No changes are planned today, but we wanted to make you aware of this."

- Do not need to wait for certainty of launch but be transparent about the uncertainties.
- Explore the patient's initial views and information needs.
- Record and stratify the response
 - A. Comfortable with a future switch
 - B. Would like more information – what in particular?
 - C. Unsure or concerned
 - D. Not currently supportive of a switch
 - E. Possible clinical or practical exception
- Record the nature of concerns
 - Loss of efficacy ● ADR ● Device or administration ● Prior experience
- Use the information to plan targeted support

Outputs:

- Patient readiness profile
- Targeted communication plan

What early planning provides

By the time the commercial position becomes clear, organisation will already have:

- An indicative value of the opportunity
- Clear governance gaps and actions
- Engaged clinical and operational leads
- A validated patient population
- A quantified capacity requirement
- A targeted communication plan
- **A clear implementation plan that can be activated when the commercial position becomes clear**

Not all answers are needed to begin planning

Earlier preparation enables faster implementation