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NHS

Medicines Optimisation

Jatinder Harchowal

Chief Pharmacist/Clinical Director, RMH

Medicines Optimisation Lead, RM Partners

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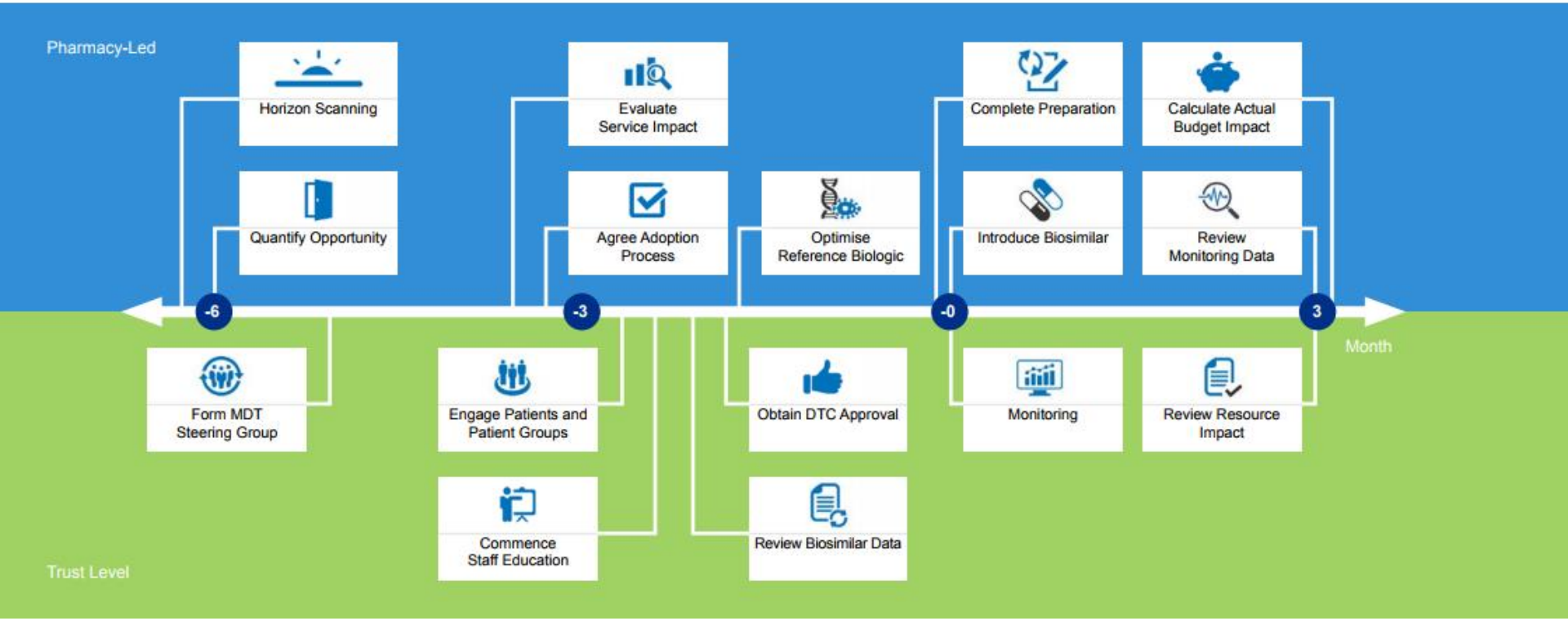
Biosimilars

NHS

Biosimilar Adoption Process Timeline



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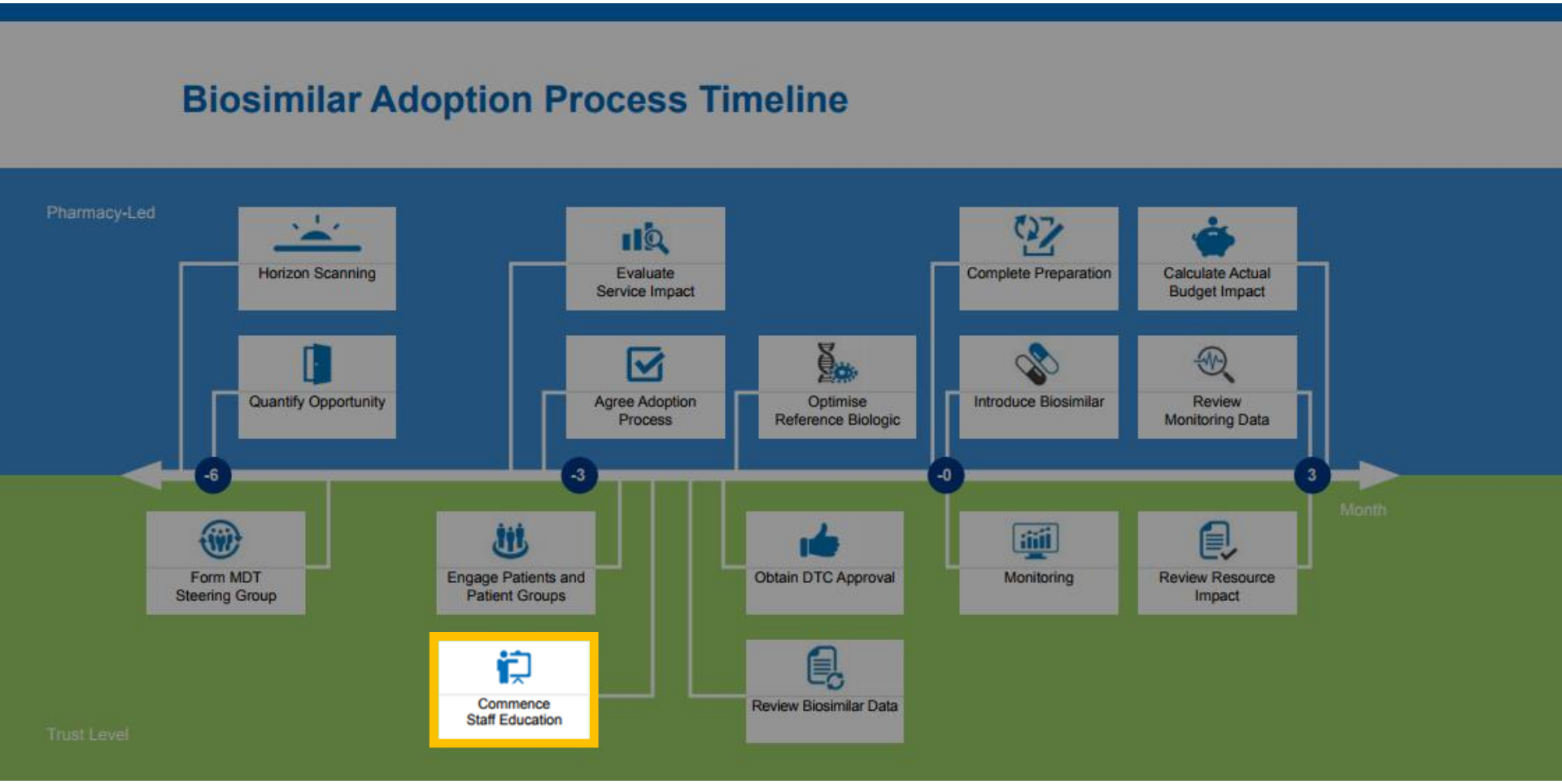
Biosimilars

NHS



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Staff Education / Comms

NHS

Commence Staff Education

Robust staff education on biosimilar principles improves the confidence of both staff and patients. Careful consideration should be given to the needs of each professional group to ensure training is as relevant and accessible to them as possible. The Vanguard has produced, piloted and validated an educational presentation. See below for link to this Biosimilar Principles educational presentation.

Checklist:

- ✓ Seek support for training from Trust management
- ✓ Identify key groups most likely to be involved in usage of this biosimilar
- ✓ Assess current level of biosimilar knowledge and preferred means of receiving training
- ✓ Where possible, conduct small group training on biosimilar principles. Consider feedback forms that allow staff to identify remaining knowledge gaps. Molecule-specific information should follow discussions on biosimilar principles
- ✓ Consider constant information updates through newsletters or questions of the week on intranet, etc.
- ✓ Ensure the way staff can get further information is clearly identified on all material
- ✓ Consider running workshops within the institution, inviting others from nearby centres with experience to contribute to programme

Timeframe: Around 3 months prior to availability

Task: Foster confidence in biosimilar concepts

Lead: Trust level

Involved: Biosimilar champions, education and training leads

Resource: Checklist, Biosimilars Educational Slide Deck, Education Impact Assessment Questionnaire, Biosimilar FAQs

Education Impact Assessment Questionnaire →

Biosimilars Educational Slide Deck →

Biosimilar FAQs →

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Staff Education / Comms

NHS

How Biologics are manufactured

Biologics are produced from living organisms

Cancer Vanguard

NHS

Variability is in the nature of biologics

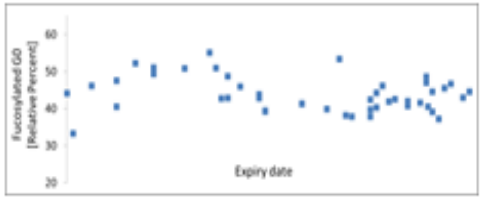
Batch-to-batch

- Non-identicalityis a normal principle in glycosylated proteins
- No batch of any biologic is 'identical' to the other batches
- Variability is natural even in the human body

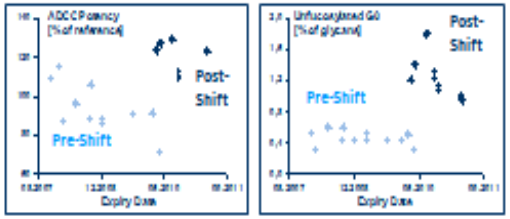
Manufacturing changes

- Manufacturing changes are made frequently
- Differences in attributes can be larger than batch-to-batch variability
- Such changes are stringently controlled by regulators and approved only if they do NOT lead to clinically meaningful differences

Variability of major glycan variant in commercial mAb



Variability of a mAb reference product



UK/MKT/BIO/17-0027d Mar 2017

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Biosimilars

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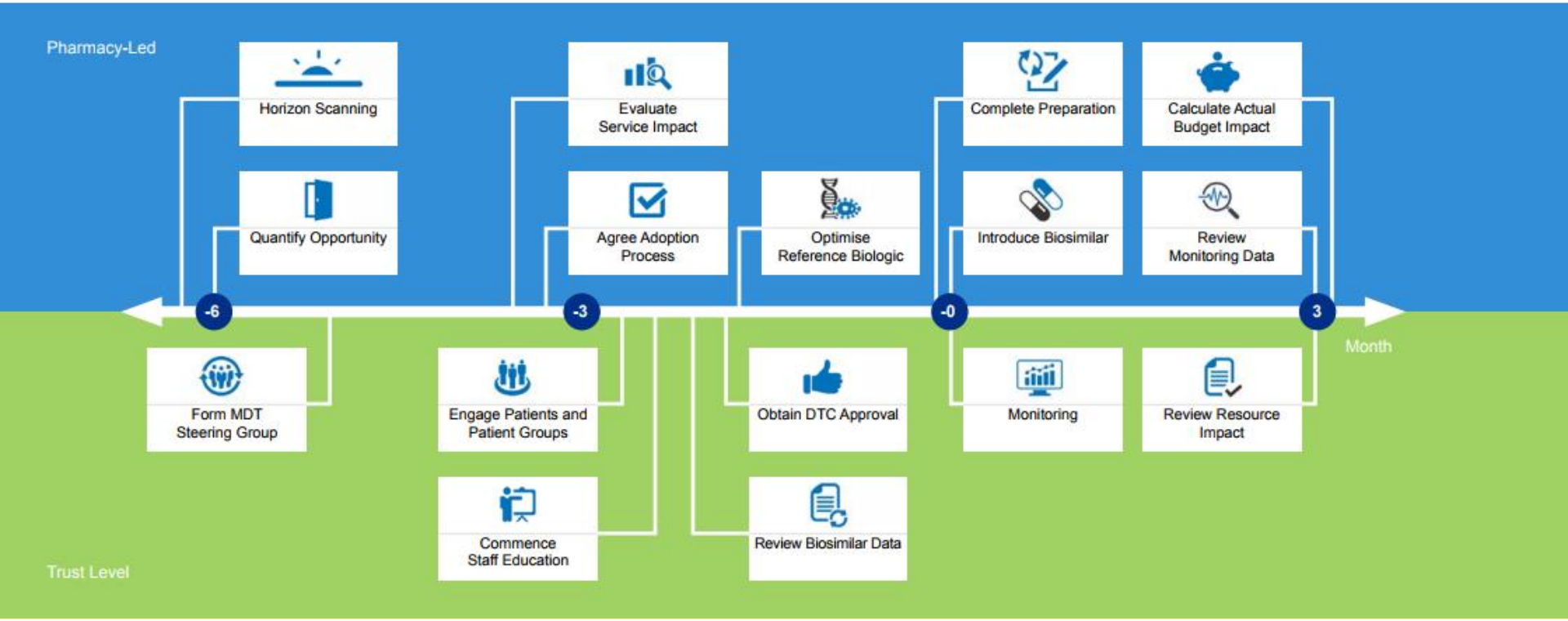
Biosimilar Adoption Process Timeline



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Biosimilars

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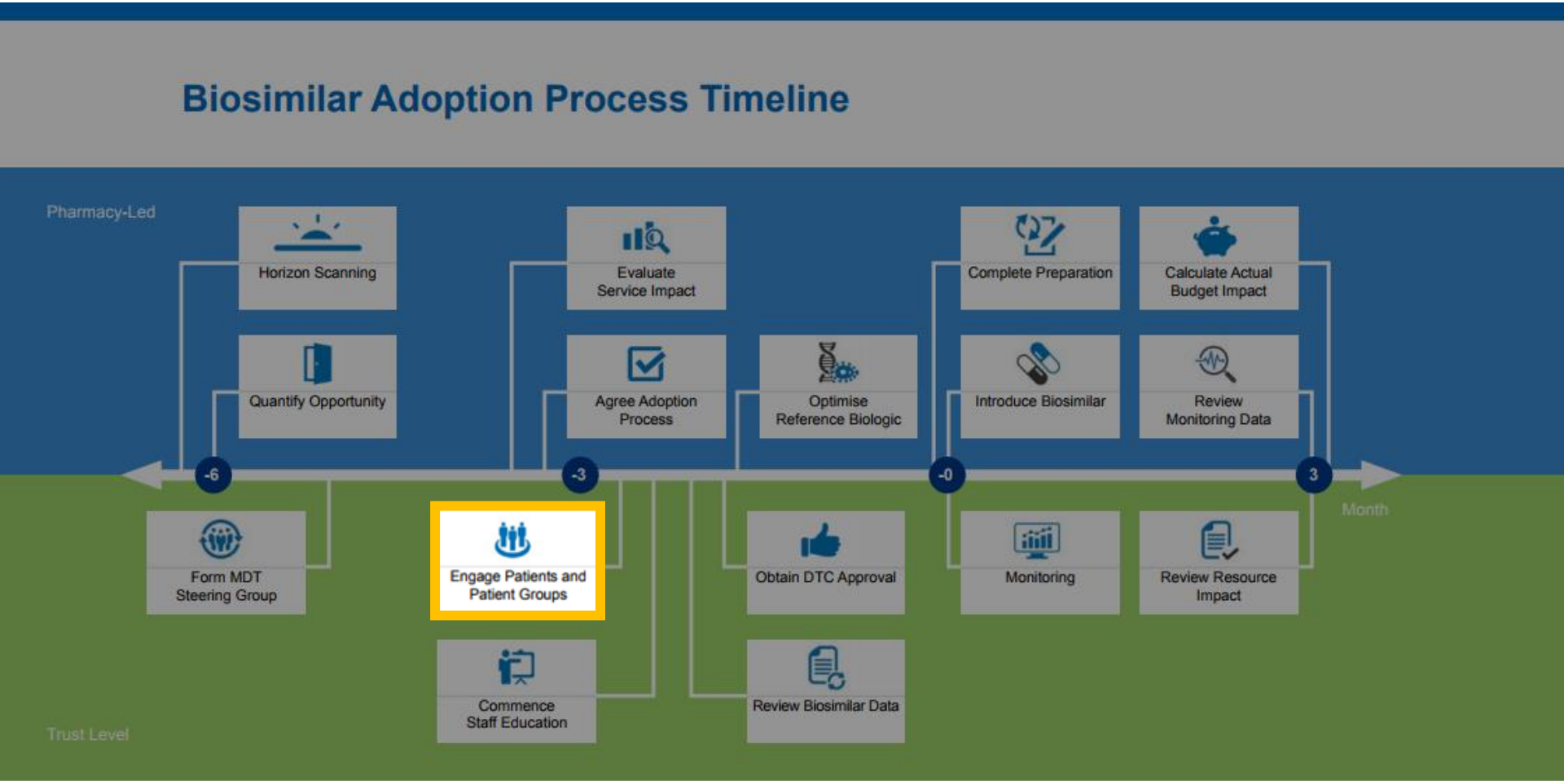

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Patient Engagement

NHS

Engage Patients And Patient Groups

As biosimilars are a relatively new technology, patients and patient groups may not be familiar with them. The patient voice must be included when making the decision to use a biosimilar. A patient panel or patient advocate should be engaged. There are examples of where this has been highly beneficial to biosimilar implementation and resulted in almost complete biosimilar usage. Click here for link to the University Hospital of Southampton experience as an example.

Checklist:

✓ Set up a meeting to engage with patients or patient forum. If a patient forum doesn't exist within the Trust, discuss obtaining equivalent input with the Patient Advice and Liaison Service (PALS) within the Trust

- The meeting should be led by a Senior Clinician/CNS/Senior Pharmacist in consultation with the PALS
- Present details of biosimilar concepts, ensure reasonable level of biosimilar understanding
- Present details of planned introduction including the opinions of leading clinicians within the Trust and expected impact to patients, the Trust and the NHS
- Listen for areas of concern or knowledge gaps. Where possible, use these as themes for the patient information leaflet or frequently asked questions. Address queries in the meeting, checking suitability of answer and impact of response to patient confidence

Timeframe: Around 3 months prior to availability

Task: Understand patient perspective

Lead: Trust level

Involved: Service lead

Resource: Statements for professional bodies and patient groups, i.e. British Society of Gastroenterology and National Rheumatoid Arthritis Society

Resources:

Lymphoma Association: Biosimilars for lymphoma

British Society of Gastroenterology position statement

National Rheumatoid Arthritis Society position statement

Patient Information Leaflet: General Biosimilar Patient Information Template for NHS Trust Use →

Patient Engagement

Co-created information:

Joint patient information with Lymphoma Association

Freephone helpline: 0808 808 5555

information@lymphomas.org.uk

www.lymphomas.org.uk

Lymphoma association

Biosimilars for lymphoma

If your treatment for lymphoma includes a biological medicine, eg rituximab, you may be treated with the original brand of medicine or a different brand – a biosimilar.

What is a biosimilar?

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Biosimilars

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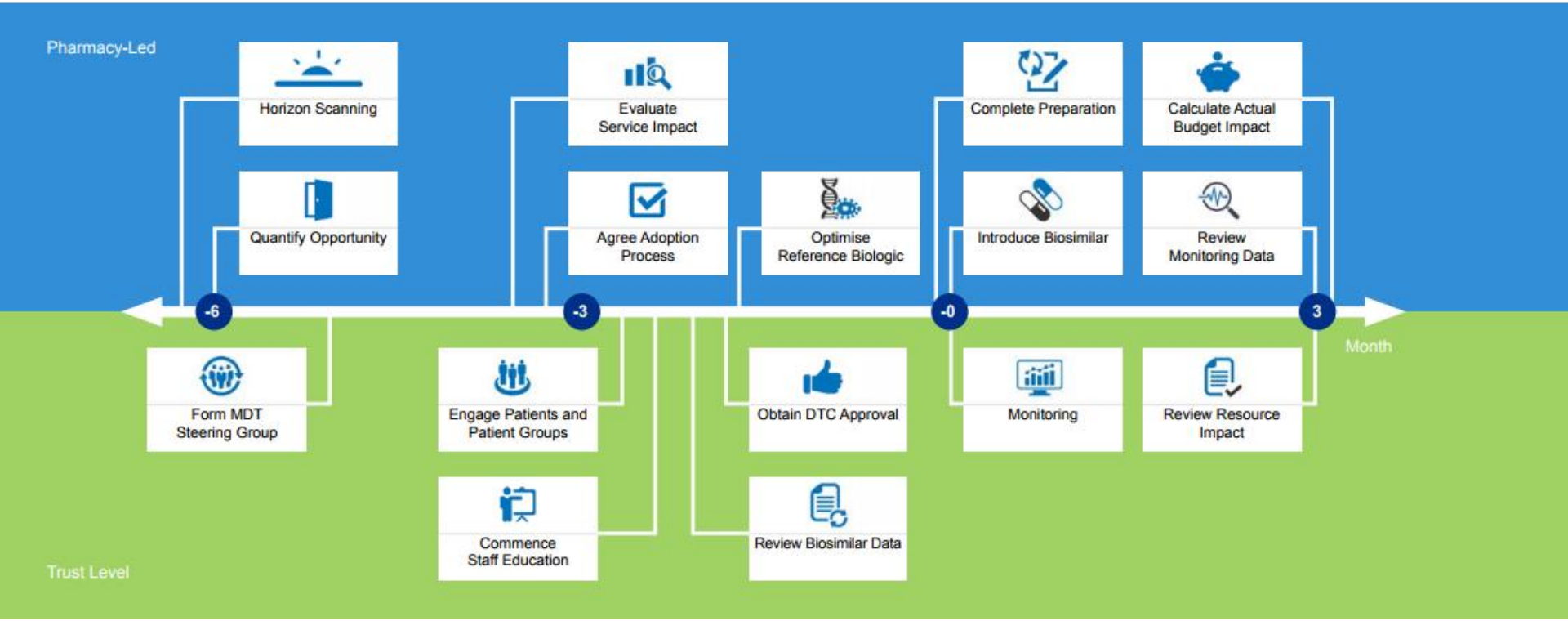
Biosimilar Adoption Process Timeline



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Experience to date

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- Complete switch to biosimilar Rituximab for all patients

- End of September 2017 in RMH and UCLH:
  - 317 patients treated with biosimilar Rituximab
  - 796 infusions
  - Mainly grade 1 and 2 reactions in line with originator

- End of Nov: 65% national uptake

- **FYE £60m savings**

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Care Closer to Home

NHS

- Explore a partnership with a third party provider to provider community pharmacy or health centre administration of low risk medicines **for all sites of RM Partners**
    - SC Trastuzamab
    - SC Denosumab
- Efficiencies in capacity and expenditure
- Economies of scale for all organisations and for third party provider

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Chemotherapy Protocols

NHS

- Standardising chemotherapy treatment protocols across London
- Allow consistent management of chemotherapy treatment for all patients
- Ensure implementation of agreed best practice guidance, across all Trusts

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Next Biosimilars….

NHS

Adoption of biosimilar Trastuzumab:

- Replicate previous biosmiliar approach for NHSE
- Biosimilar Trastuzamab – May 2018
- £57m spent on IV formulation in NHSE
- Engaging ‘Breast Cancer Care & ‘Breast Cancer Now’ to produce a national patient information leaflet

Engagement

Engagement with Community Pharmacies

- RM Partners Low Dose CT Screening for Lung Cancer project

- Support referrals from community pharmacists
  - improve early diagnosis
  - support smoking cessation

- Out of hospital pick up meds from local pharmacy

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Examples of Protocol

NHS

LONDON CANCER ALLIANCE West and South

Lung Pathway Group – Crizotinib in Non-Small Cell Lung Cancer (NSCLC)

Indication:	Treatment option in previously treated Anaplastic Lymphoma Kinase (ALK) positive advanced NSCLC
NCDF criteria	ALK +ve advanced or metastatic non-small cell lung cancer 2nd or subsequent line treatment post 1st line combination chemotherapy Eligible for patients able to tolerate and comply with oral dosage forms.
Regimen details:	Crizotinib 250mg PO Twice daily continuously
Administration:	Crizotinib available as 200mg and 250mg hard capsules. Swallow whole. Take with or without food
Frequency:	Dosing is continuous, until disease progression or unacceptable toxicity
Pre-medication:	Not routinely required
Anti- emetics:	Minimal emetogenicity Follow local anti-emetic policy
Supportive medication:	Diarrhoea can be managed with loperamide. Mouthcare as per local policy. Various approaches may be considered to deal with skin reactions including rash, acne type reactions, erythema/ pruritus, dryness or blistering (topical emollients, cleansers or possibly anti-infective creams). Urea containing creams may be beneficial to treat dry skin. Support use of non-deodorant, non-fragrance products. Consider

Lung Pathway Group – Crizotinib in Non-Small Cell Lung Cancer (NSCLC)

	products with anti-itch additions in pruritus, and exfoliating products in hyperkeratosis. Anti-dandruff shampoo may help in management of itchy scalp. Analgesia may help but a 1-2 week dose interruption may be necessary for painful and severe symptoms. Rashes usually resolve rapidly upon cessation of treatment.
Extravasation:	Not applicable
Regular investigations:	Prior to Cycle 1: ALK or ROS1 assay FBC — Day 1 (within 14 days) LFTs (incl. AST, ALT) — Day 1 (within 14 days) U&Es — Day 1 (within 14 days) Imaging — Baseline ECG — Baseline and periodic monitoring as clinically indicated LFTs (incl. AST, ALT) — Every 2 weeks for the first 2 cycles Prior to Day 1 (all cycles): FBC — Monthly LFTs (incl. AST, ALT) — Monthly U&Es — Monthly Imaging — After 3 months
Toxicities:	Hepatic failure and increased transaminases, risk of QT prolongation, heart failure, neutropenia, pneumonia, visual effects, nausea, vomiting, decreased appetite, diarrhoea, oedema, constipation, fatigue, neuropathy, dysgeusia.

DOSE MODIFICATIONS

Dosing interruption and/or dose reduction may be required based on individual safety and tolerability.
If dose reductions are necessary, then the dose of Crizotinib should be reduced to **200mg twice daily**.
If further dose reduction is necessary, then reduce to **250mg once daily**.