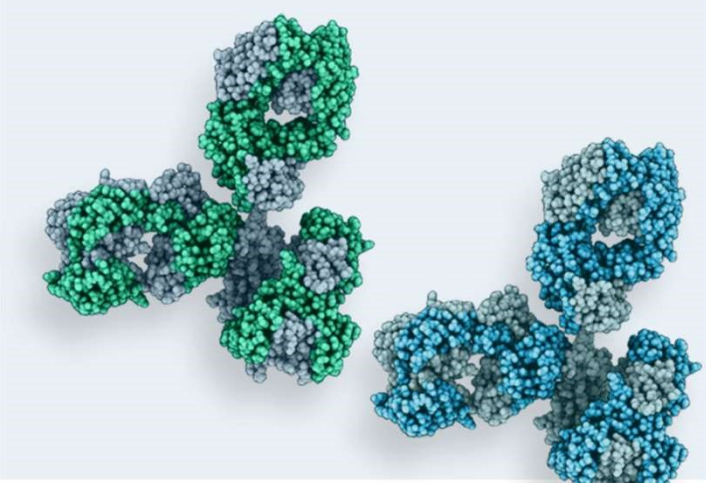
International Society of Nurses in Cancer Care

BIOsim

A train the trainer programme for nurses

Module 2



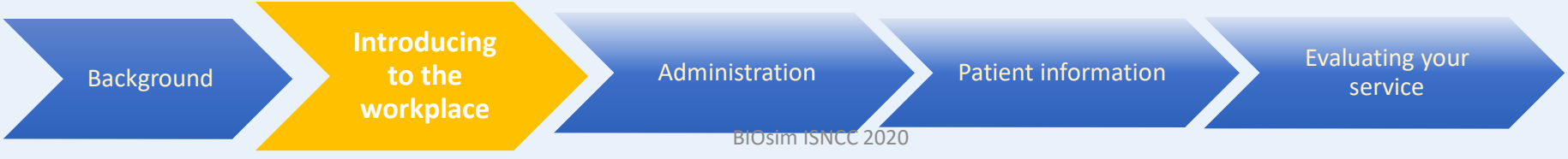
(Supported by an unrestricted grant from Pfizer)

Introducing biosimilars into the workplace

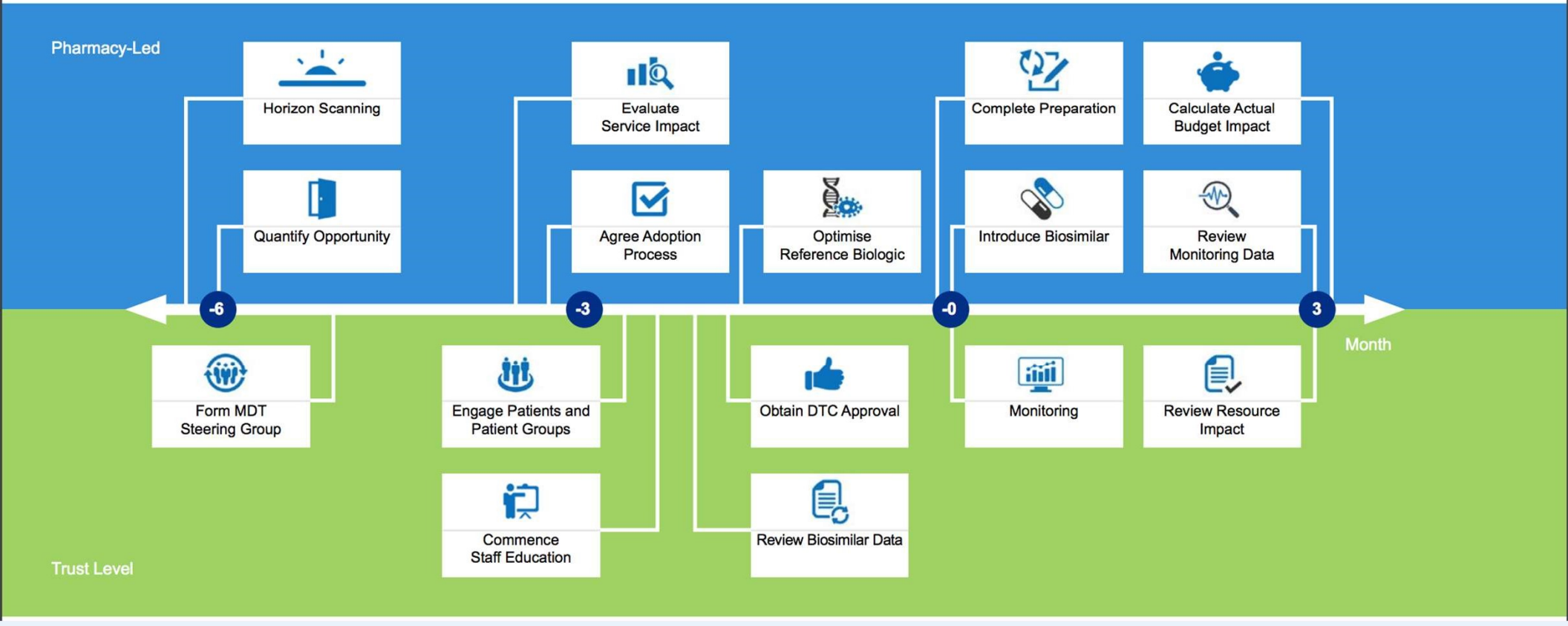
Objectives of the session

At the end of this session the nurse will be able to,

- Appreciate the leadership required to introduce biosimilars into practice
- Consider the varying stakeholder views with regard to biosimilars
- Consider the use of planning tools to develop practice
- Understand the training requirements of staff
- Understand the changes required to current practice
- Be aware of the implications in relation to clinical trials
- Evaluate the service



Biosimilar Adoption Process Timeline

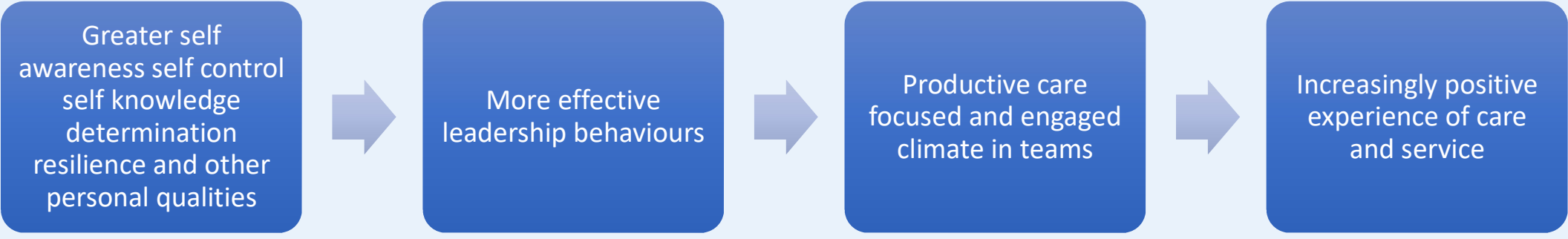


leadership
people
leader
leaders
Leading
Managing
Communication
Building
developing
Motivating
management
others
change
like
learn
Servant
without
employees
topic
lead
SKILL
self
interested
global
teams
just
difficult
strategic
team
new
Service
role
organization
vision
effective
Dealing
convincing
provide
community
employee
Keep
get
want
idea
mindset
one
corporate
cultures
Imagination
Social
member
politics
results
excellence
motivate
support
confidence
values
attended
someone
improvement
customer
shorter
aggressive
techniques
Anything
successful
act
current
Sustainability
best
Power
emphasis
strengths
staff
times
freedom
partner
face
Generation
float
Board
experience
planning
right
year
conversation
use
reasons
motivation
deal
world
one's
left
look
Training
Courage
multi
engagement
discuss
Millennials
think
mistakes
continue
struggle
roll
inspire
workplace
workers
relationships
time
work
worldviews
level
explore
organizations
need
ways
companies
skills
problem
diverse
conduct
and/or
business
recognize
Hiring
well
help
solving
understanding
many
decision
Collaboration
Speaking
generations
innovation
middle
working
group
general
Courageously
develop
effectively
Collaborative
goals
manage
getting

Leadership

Think of a good leader
What makes them good ?

Personal attributes at any level of leadership are important



Bass, B.M (1992), in M. Syrett and C. Hogg (Editors), Frontiers of Leadership. Oxford: Blackwell

Two models of leadership will be discussed but there are others..

- The NHS Healthcare model
- Kouzers and Posner

The NHS Healthcare leadership model

Inspiring shared purpose	Leading with care	Evaluating information
Connecting our service	Sharing the vision	Engaging the team
Holding to account	Developing capability	Influencing for results

https://www.leadershipacademy.nhs.uk/wp-content/uploads/2014/10/NHSLeadership-LeadershipModel-colour.pdf

1 MODEL the Way

1. **FIND YOUR VOICE** by clarifying your personal values.
2. **SET THE EXAMPLE** by aligning actions with shared values.

2 INSPIRE a Shared Vision

3. **ENVISION THE FUTURE** by imagining exciting and ennobling possibilities.
4. **ENLIST OTHERS** in a common vision by appealing to shared aspirations.

3 CHALLENGE the process

5. **SEARCH FOR OPPORTUNITIES** by seeking innovative ways to change, grow, and improve.
6. **EXPERIMENT AND TAKE RISKS** by constantly generating small wins and learning from mistakes.

4 ENABLE Others to Act

7. **FOSTER COLLABORATION** by promoting cooperative goals and building trust.
8. **STRENGTHEN OTHERS** by sharing power and discretion.

5 ENCOURAGE the Heart

9. **RECOGNIZE CONTRIBUTIONS** by showing appreciation for individual excellence.
10. **CELEBRATE THE VALUES AND VICTORIES** by creating a spirit of community.

http://www.pnbhs.school.nz/wp-content/uploads/2015/11/The-Five-Practices-of-Exemplary-Leadership.pdf

Leadership

- Attending to these leadership aspects are associated with a high degree of success in terms of project management.

Getting started

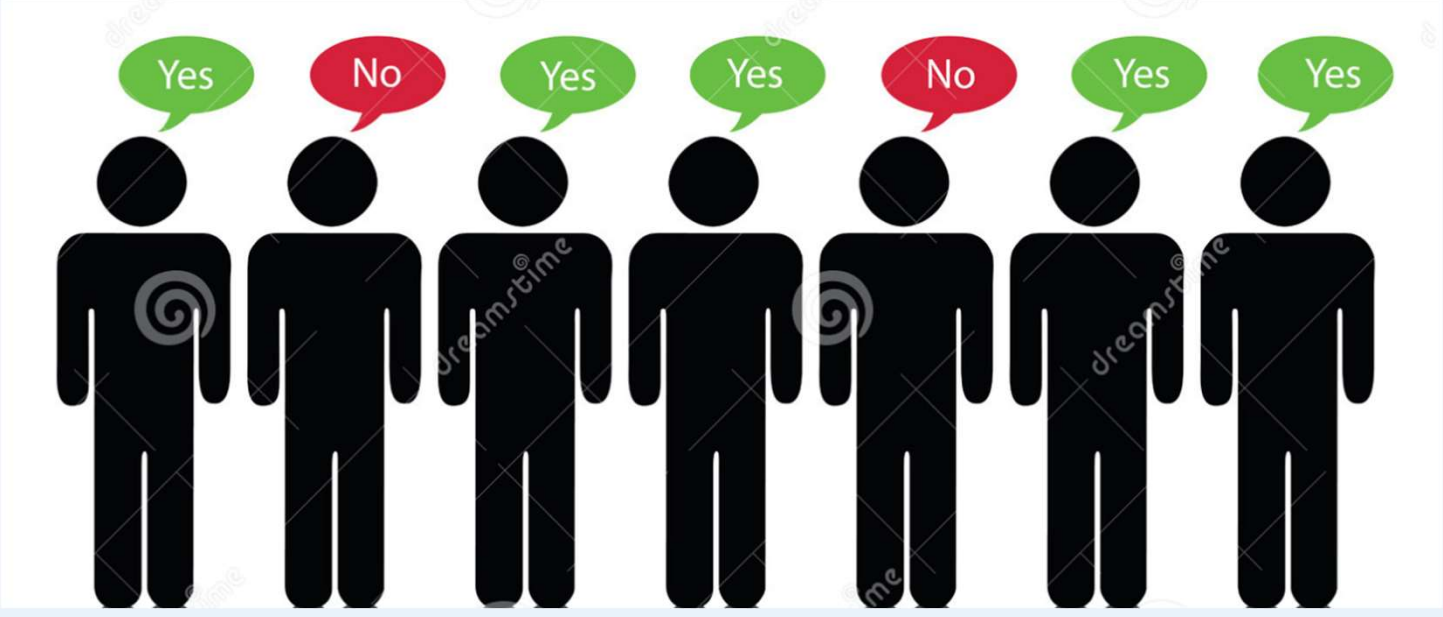
- Begin the vision
- Start a narrative
- Understanding the local setting
- Stakeholder engagement
- Project plan

- https://www.youtube.com/watch?v=GA8z7f7a2Pk

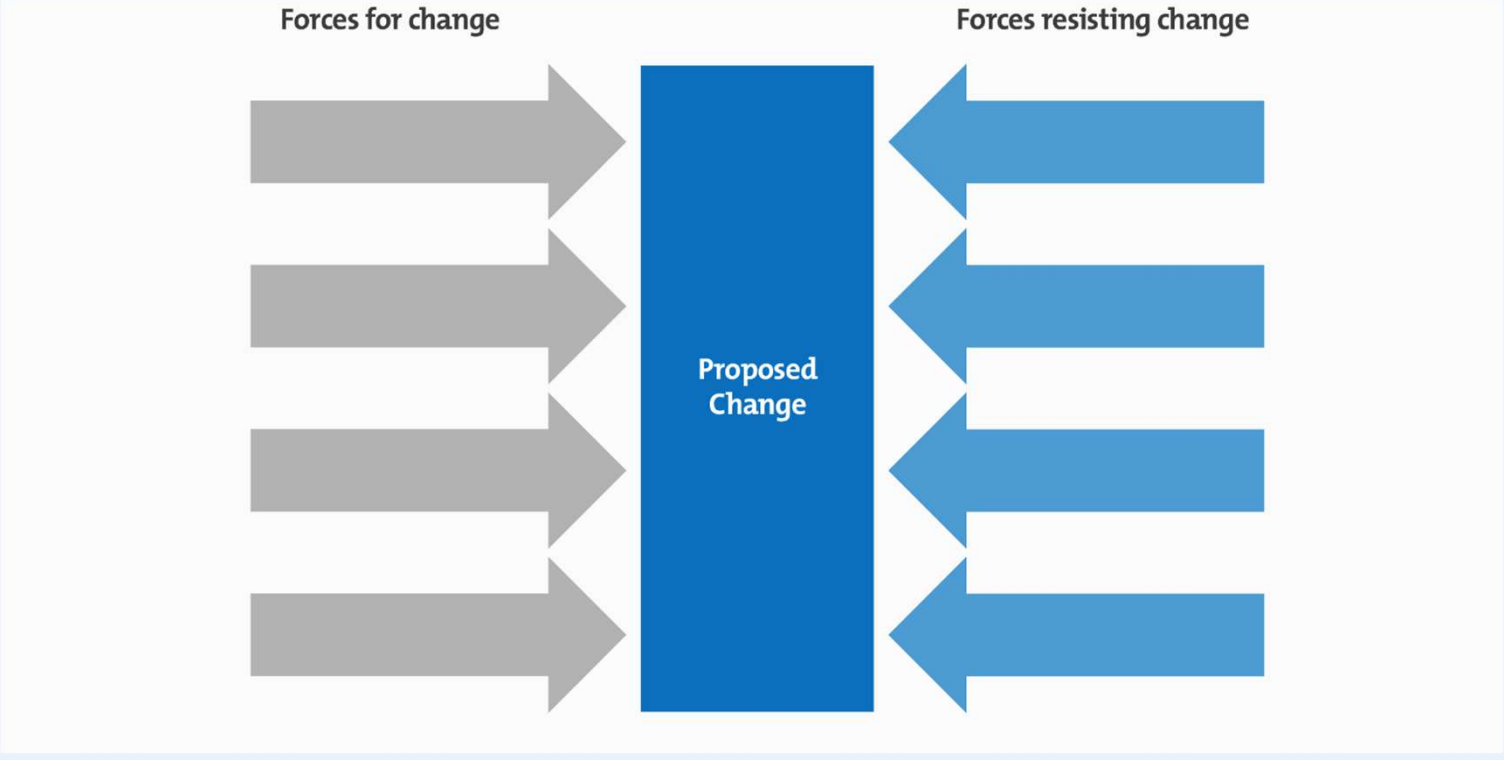
- https://www.youtube.com/watch?v=hO8MwBZl-Vc

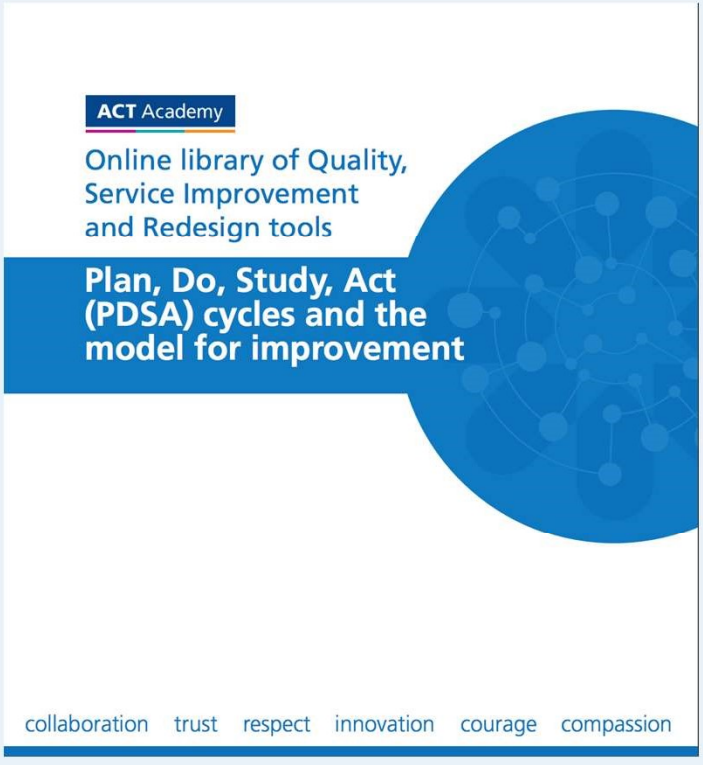
Stakeholder engagement

- Not everyone may be keen to introduce biosimilars to practice but it is essential to have a medical champion.



Force field analysis to understand views

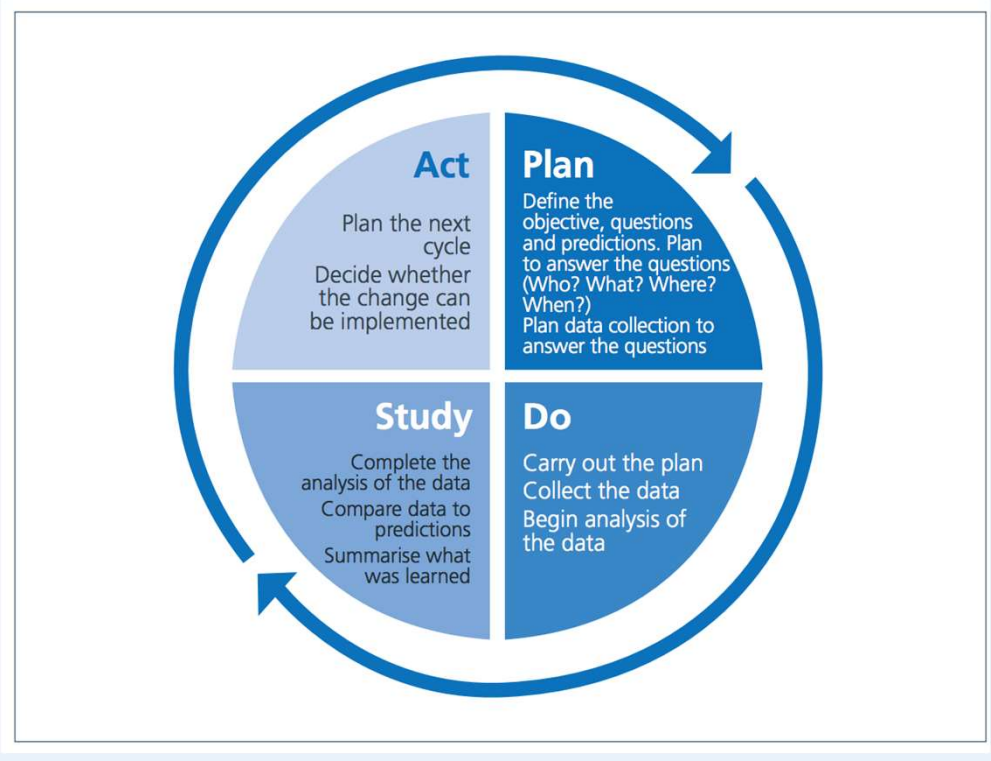




https://improvement.nhs.uk/documents/2142/plan-do-study-act.pdf

http://www.kingsimprovementscience.org/kis-QI-guide-step-3

Project planning



TEAM: **Date:**

AIM **Question you want answered with this test:**

Describe your first (or next) test of change	Person responsible	When to be done	Where to be done

PLAN

List the tasks needed to set up this test of change	Person responsible	When to be done	Where to be done

DO **RUN THE TEST**

STUDY

Describe what actually happened when you ran the test

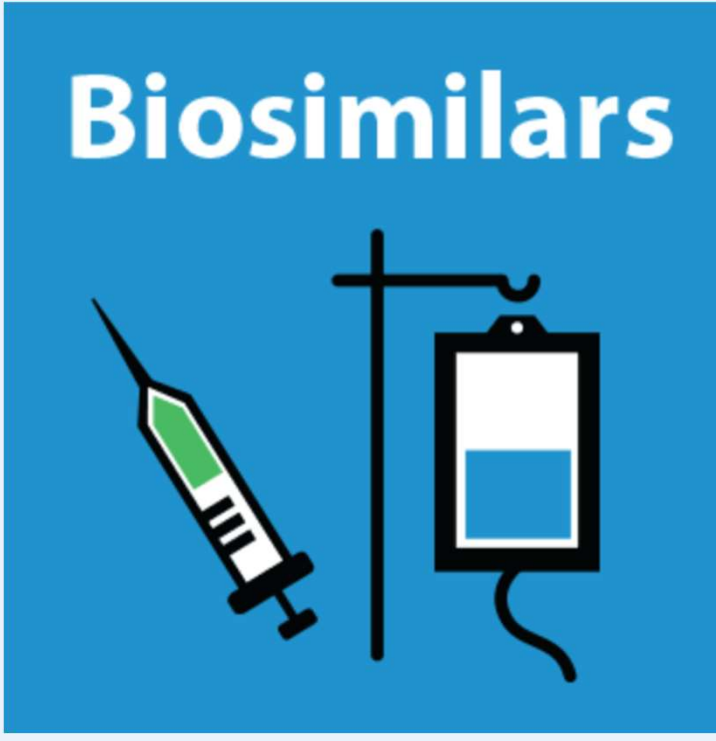
Describe the measured results and how they compared to the predictions and what you learned from the cycle

ACT

Describe modifications for the next cycle based on what you learned

Countdown to switch

- All patients advised
- All patients , new or transition
- Stock of biosimilar
- Prescribing systems ready
  - Prescription
  - Labels
- Nursing staff education



Staff education vital prior to implementation

Needs analysis

Topics for education

- Language of biosimilars
- Branding
  - Determine by trust
- Supply
  - Led by pharmacy
- Prescribing
  - Prescribers information
  - Changes to electronic prescribing systems
- Labeling
  - Led by pharmacy
- Toxicities
  - Administration and post administration
- Timing
  - Administration differences
- Patient support
  - CNS and chemo nurse

Clinical trial

- May still require originator drug in practice so consider safety

Important differences

- Brand name MUST be used for prescribing
- Interchangabiity of brands not recommended
- Administration should be the same as originator
- Reactions may be difference by brand/batch

Evaluating the service is important

Cancer Vanguard

NHS

Post-authorisation activities

- As for any biopharmaceutical, the clinical safety of biosimilars must be monitored through continued pharmacovigilance
  - A pharmacovigilance plan must be adopted
    - Involves collection and assessment of AE data, post-approval studies and registries
  - The need for risk minimisation strategies must be evaluated
    - Assesses whether strategies are needed beyond the pharmacovigilance plan
  - A risk management plan must be submitted
    - Typically includes the same obligations and activities as for the reference medicine

European Medicines Agency (EMA). Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues. EMEA/CHMP/BMWP/42832/2005 Rev. 1. (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2013/06/WC500144124.pdf) [Accessed 2016 March 23].

Summary

- Leadership is key to any project management. A medical champion is a MUST
- A framework for the project is helpful in developing milestones and timelines
- Not all stakeholders will be enthusiatic
- Education is vital
- Post implementation audit is important

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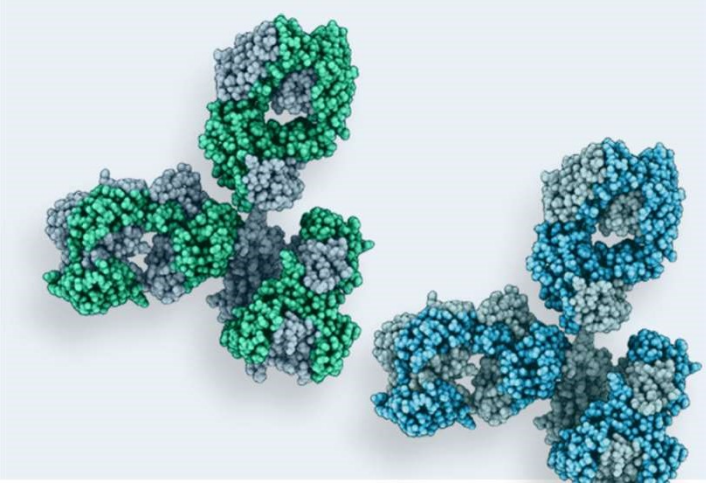
Questions?



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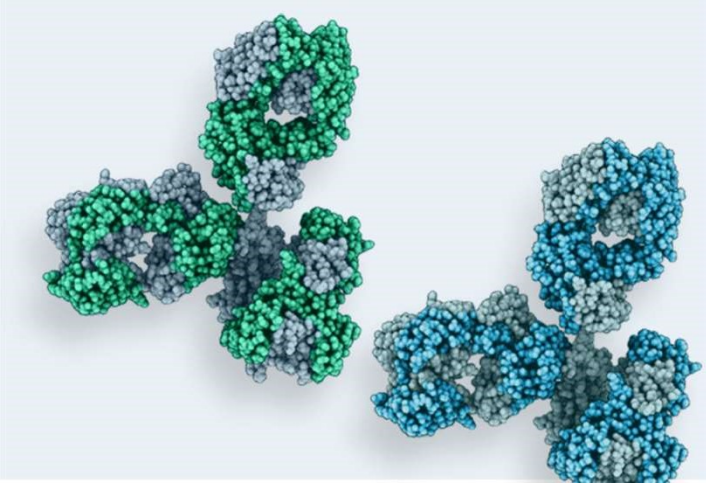

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