

## Diagnostic Evidence Co-operative Leads

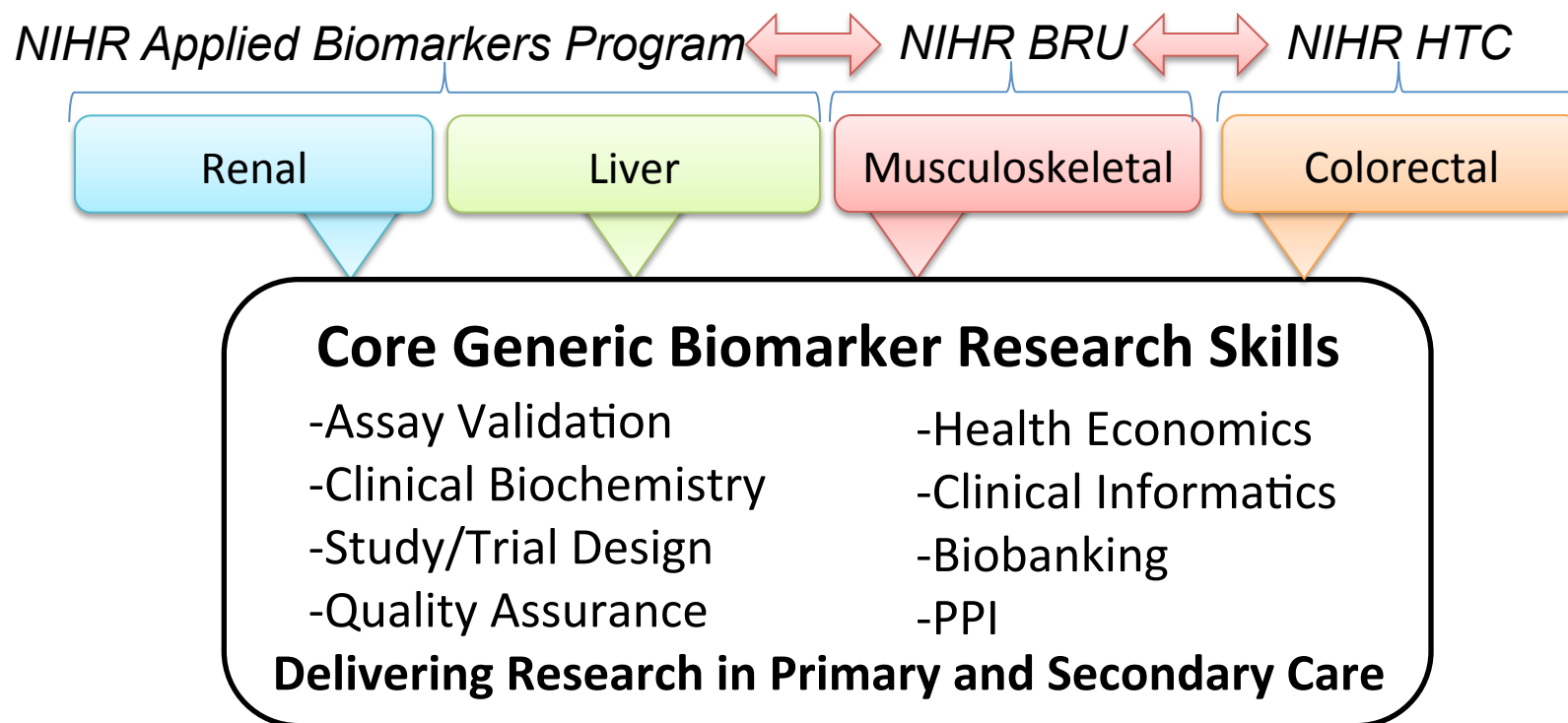
# Introduction and Overview

Michael Messenger, Deputy Director



A partnership between the NHS, patients, academia, industry and charities

# DEC Leeds: Scope & Skills



Diagnostics; Prognostics; Monitoring; and Prediction/Stratified Medicine

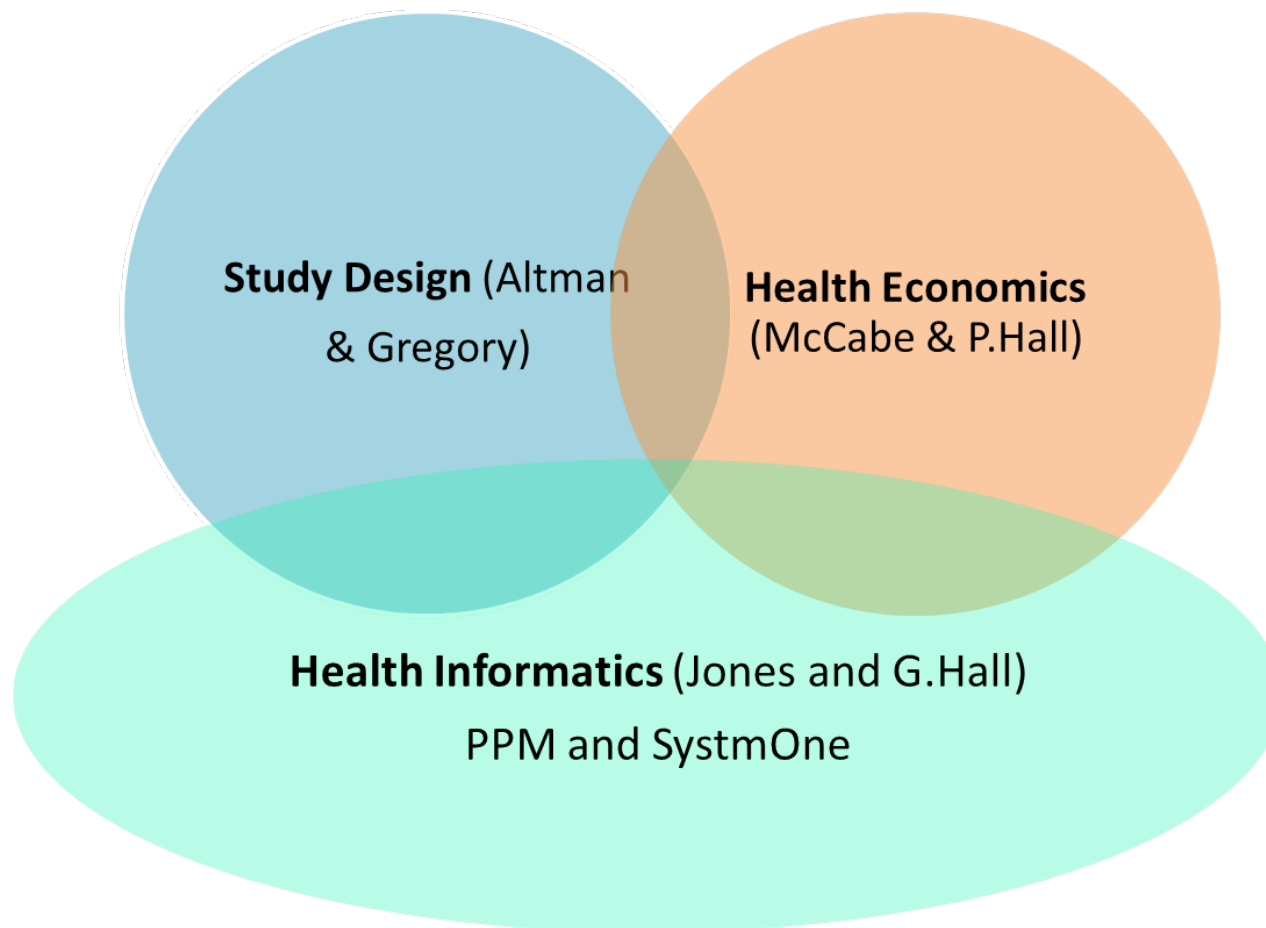
# Industry Facing

- *Research facilitation:*
  - early stage project planning and feasibility
  - identify commercial and non-commercial partners
  - collaborative & contract research
  - funding opportunities (UK SMEs)
  - consortia building.
- *Standardised processes:*
  - GCP and GCLP
  - confidentiality agreements
  - costing templates.

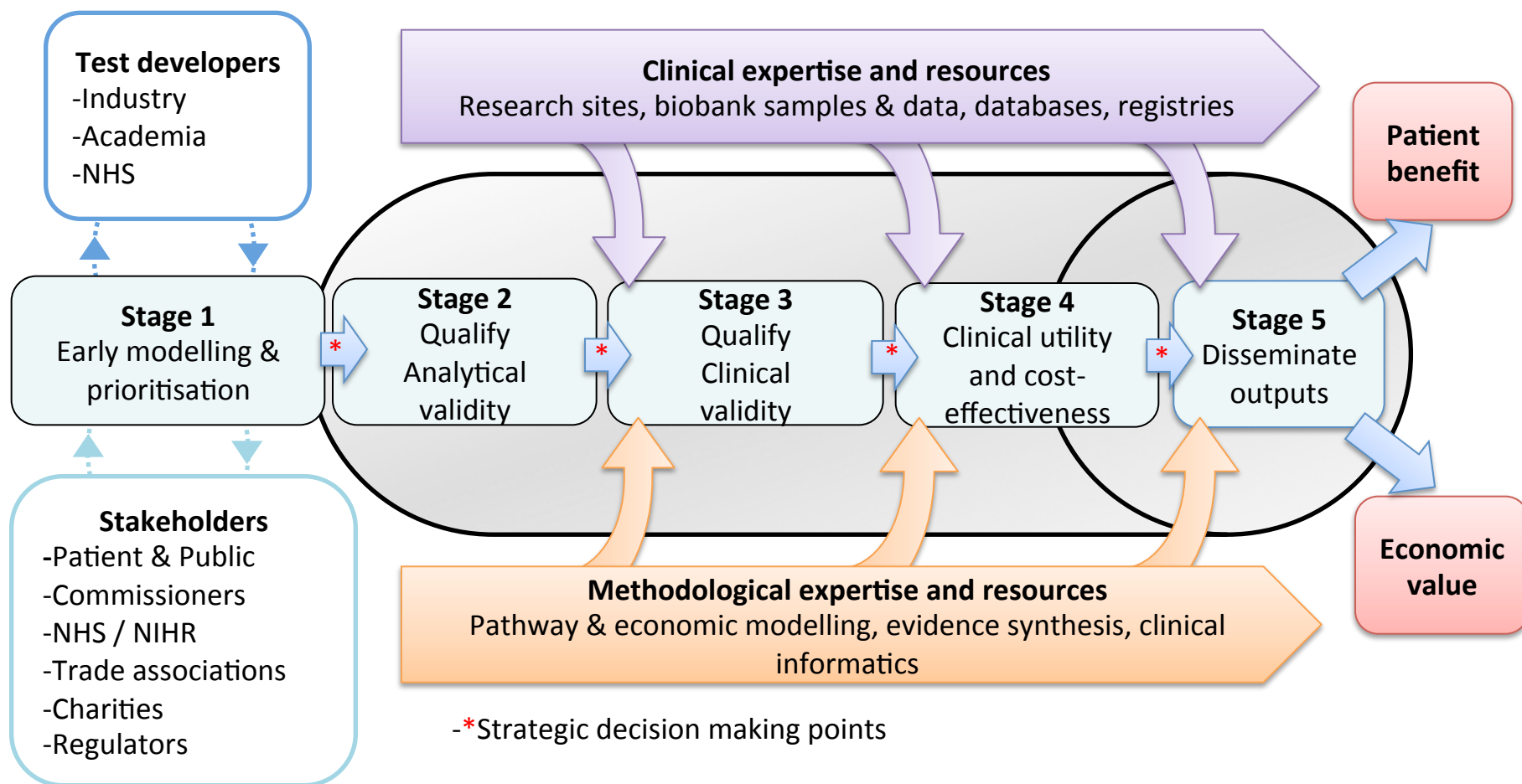


# Biomarker Evaluation Methodology

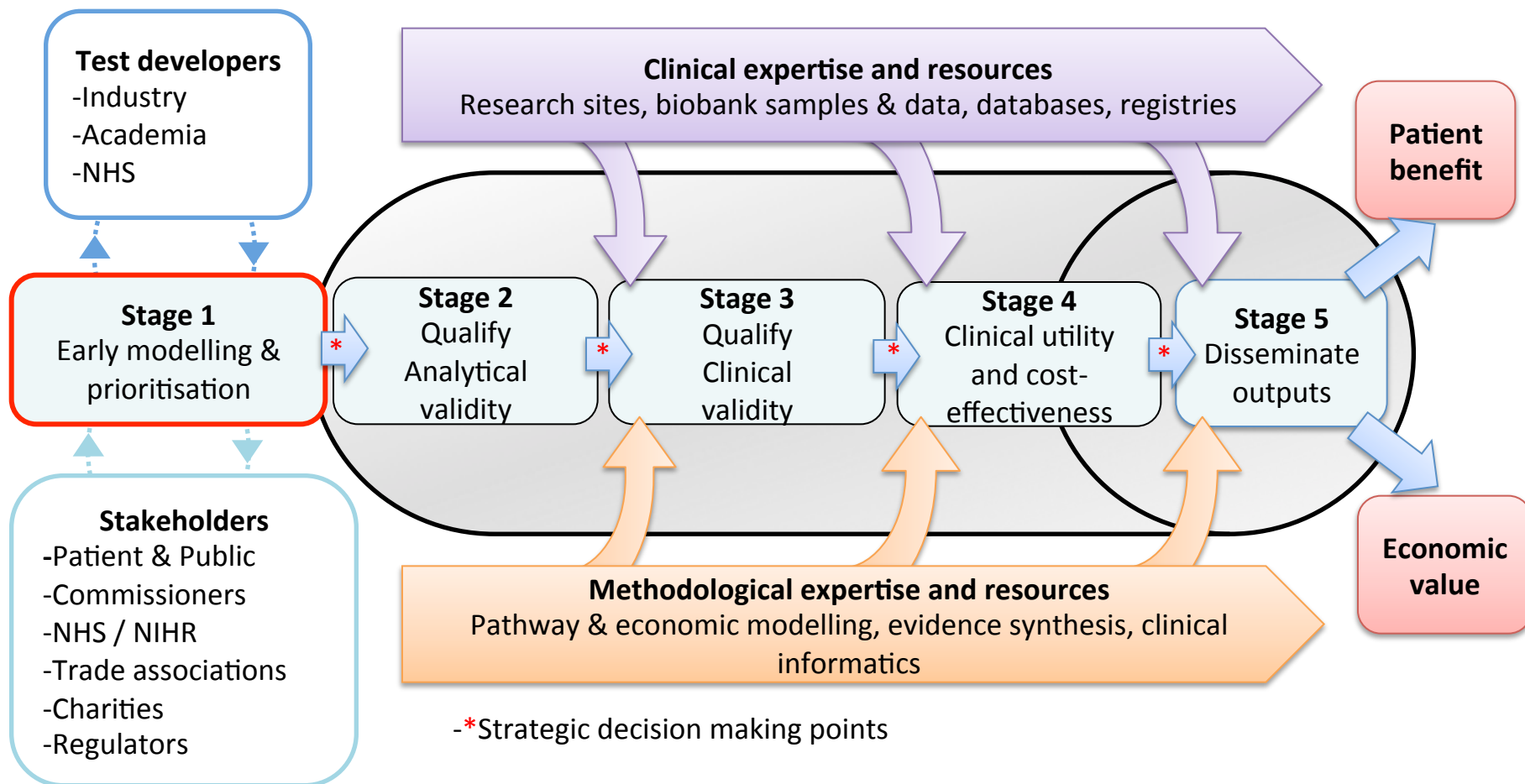
Research to improve the evidence generation process



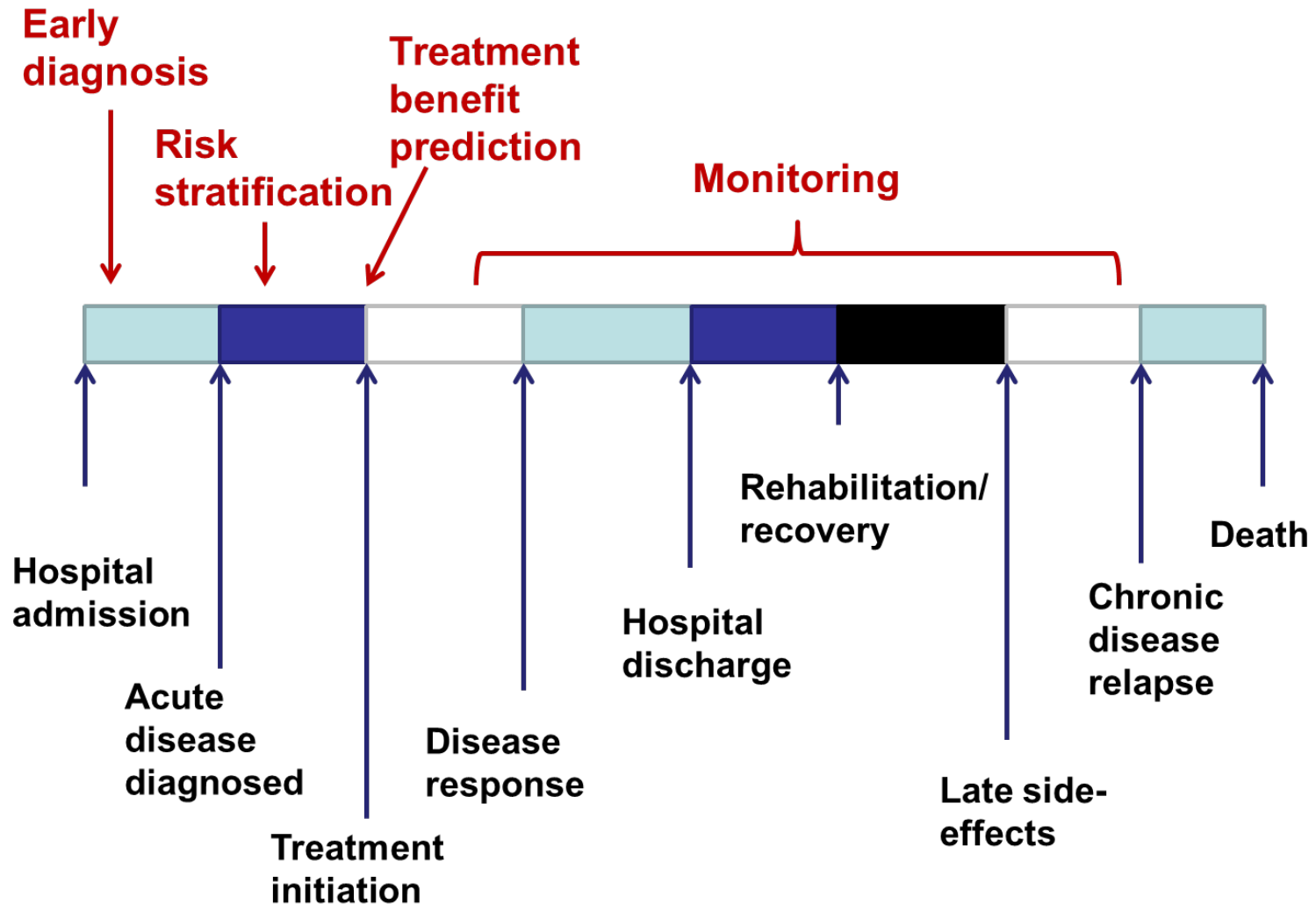
# DEC Leeds: Evidence Generation



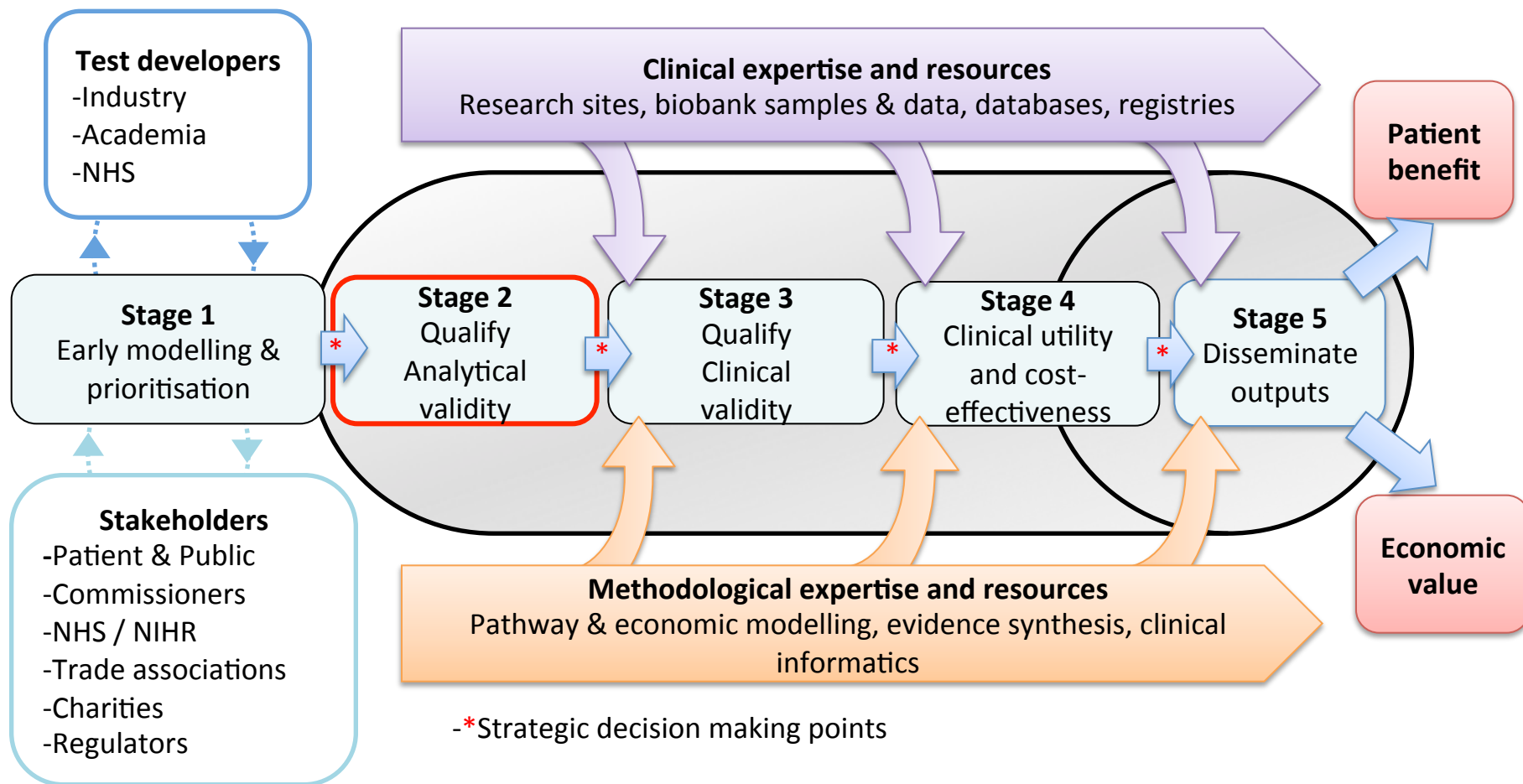
# DEC Leeds: Evidence Generation



# Early modelling



# DEC Leeds: Evidence Generation



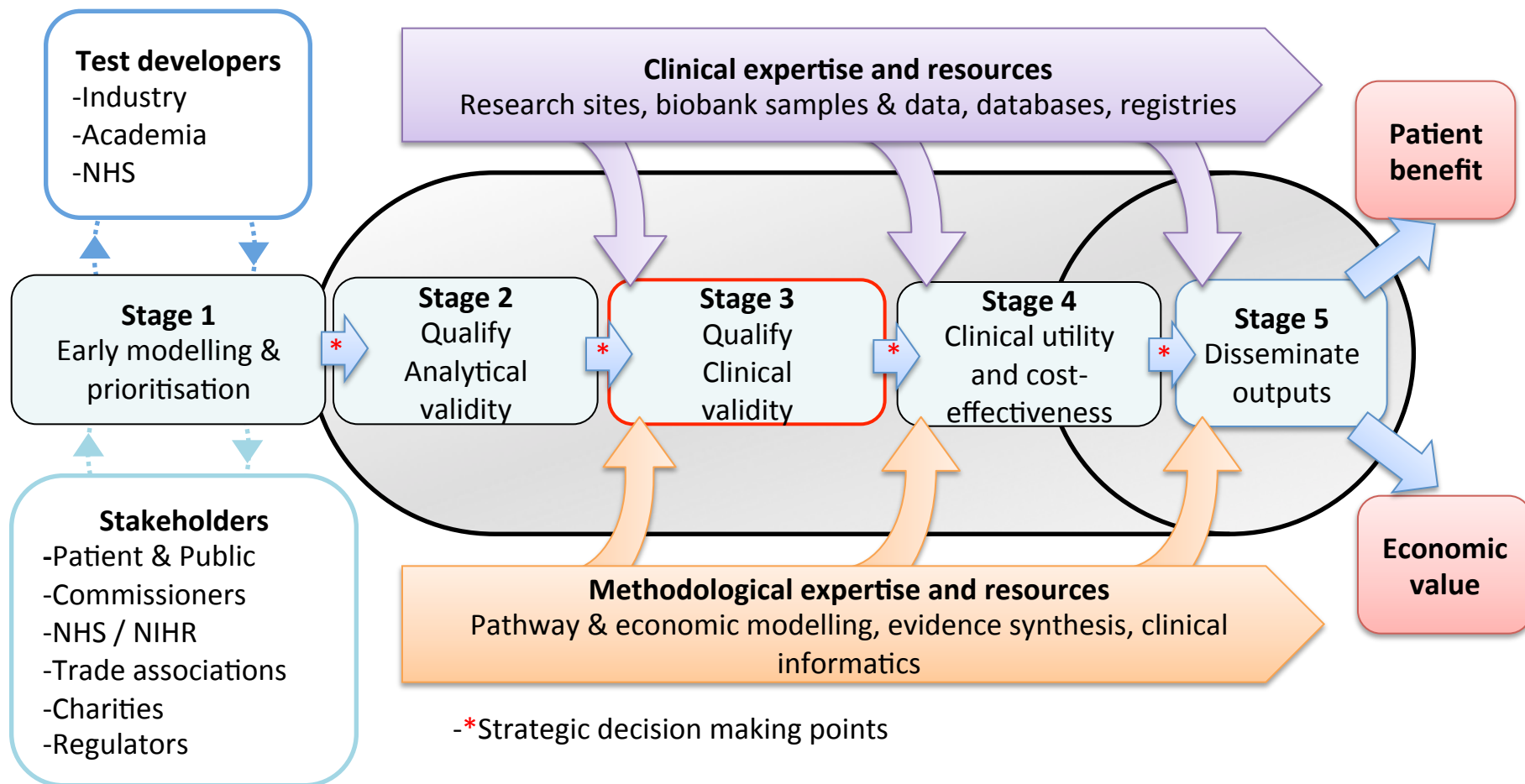


# Qualify Analytical Validity

- Surplus diagnostic samples
- Evaluate influence of pre-analytical factors
- Method validation
- Method comparison
- External quality assessment

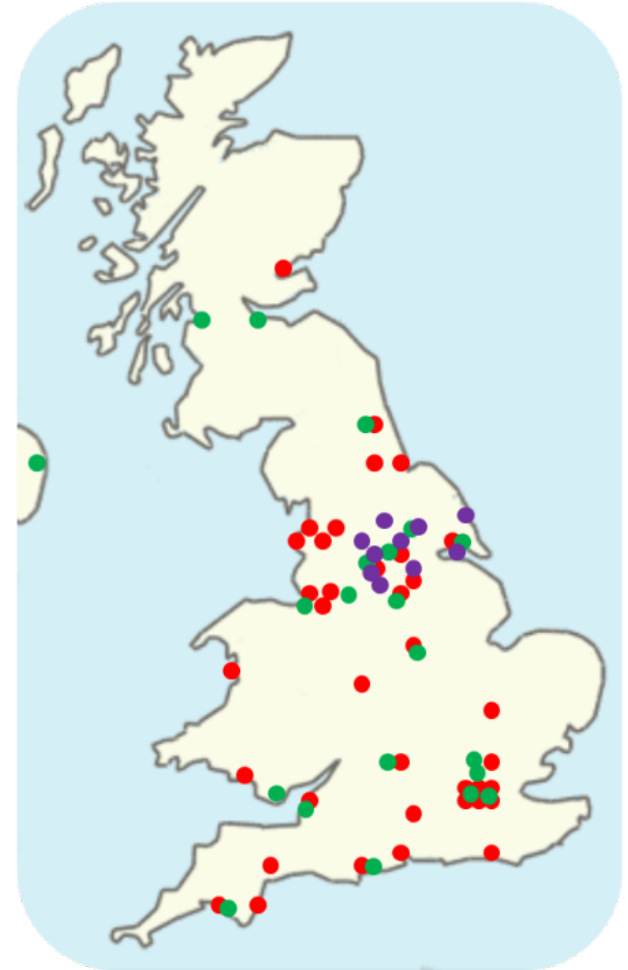


# DEC Leeds: Evidence Generation

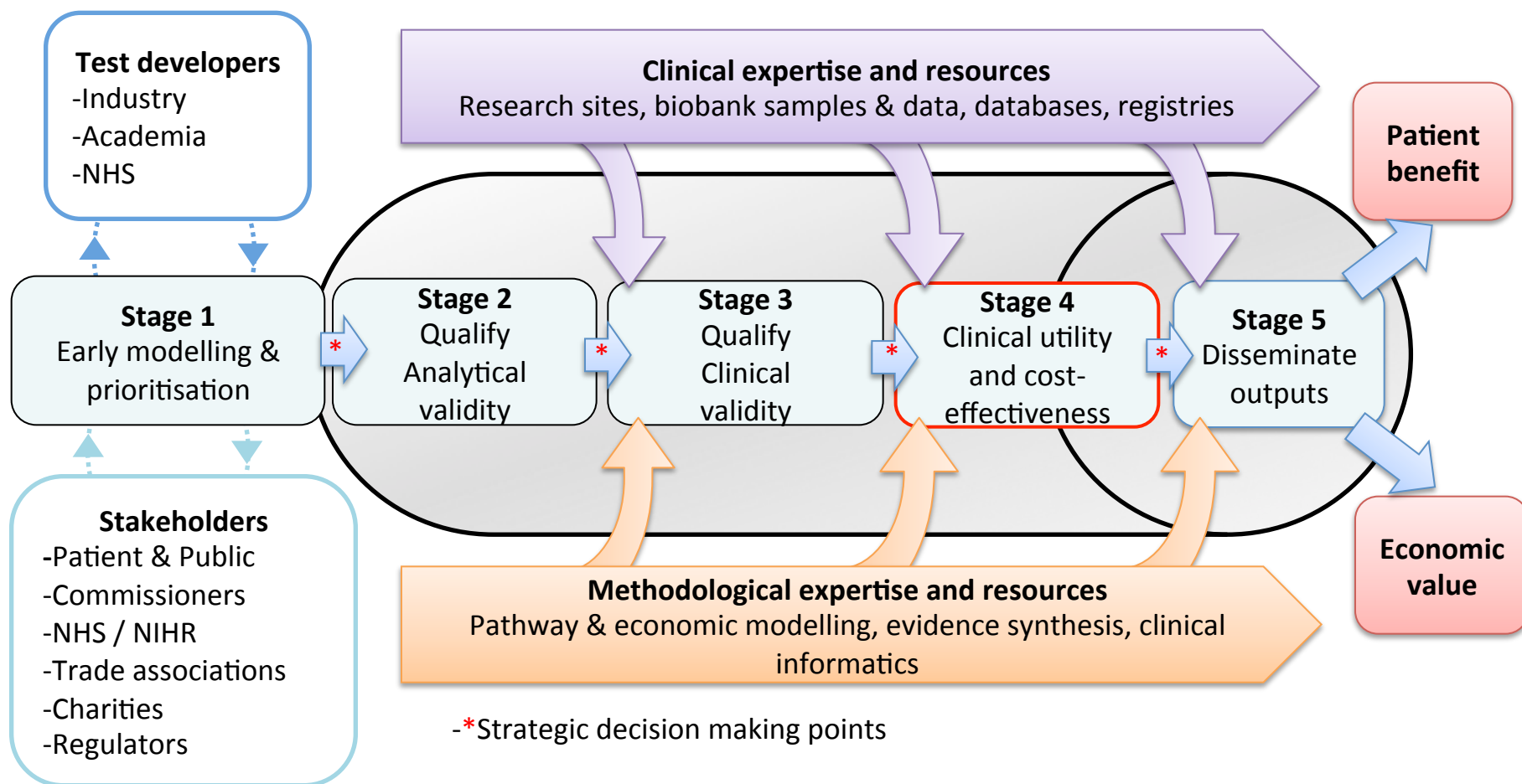


# Qualify Clinical Validity

- Prospective collection of high quality:
  - patient samples
  - clinical data
- Study design and conduct
- Biostatistical analysis



# DEC Leeds: Evidence Generation



# Clinical Utility

- Patient cohorts
- Efficient trial methods
- Health informatics
  - use of routine NHS datasets
- Decision analytic modelling
- Clinical decision algorithms



# Cost-Effectiveness

- Model-based economic evaluation
- Health informatics (integrated economic data collection)
- Value of information analysis



# Summary

## The Diagnostic Evidence Co-Operative Leads:

- Facilitates the generation of research on in vitro diagnostic tests
- Adopts an evolving model based research strategy that can:
  - evaluate clinical and commercial value
  - prioritise research and efficient study designs
  - prevent expensive biomarker failures

# Acknowledgements

- All the DEC Leeds collaborators and partners
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