

# Diagnostic Test Evaluations Workshop: The pathway of evidence generation



Wednesday 10<sup>th</sup> April  
13:00 – 17:30

Join the conversation!



@NIHR\_NCL\_MIC  
#evidencepathways\_NCL\_MIC  
#DiagnosticsNE

wireless SSID "Mobilise" password: M57wr72bG





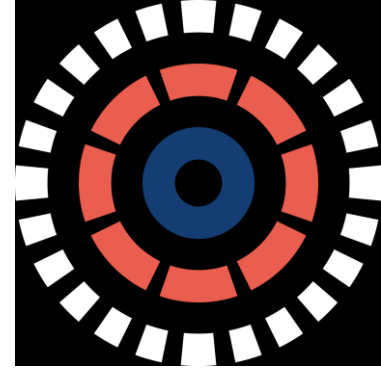
# Introduction to the day and to the evidence development pathway

Dr Sara Graziadio



10/04/2019, Newcastle upon Tyne

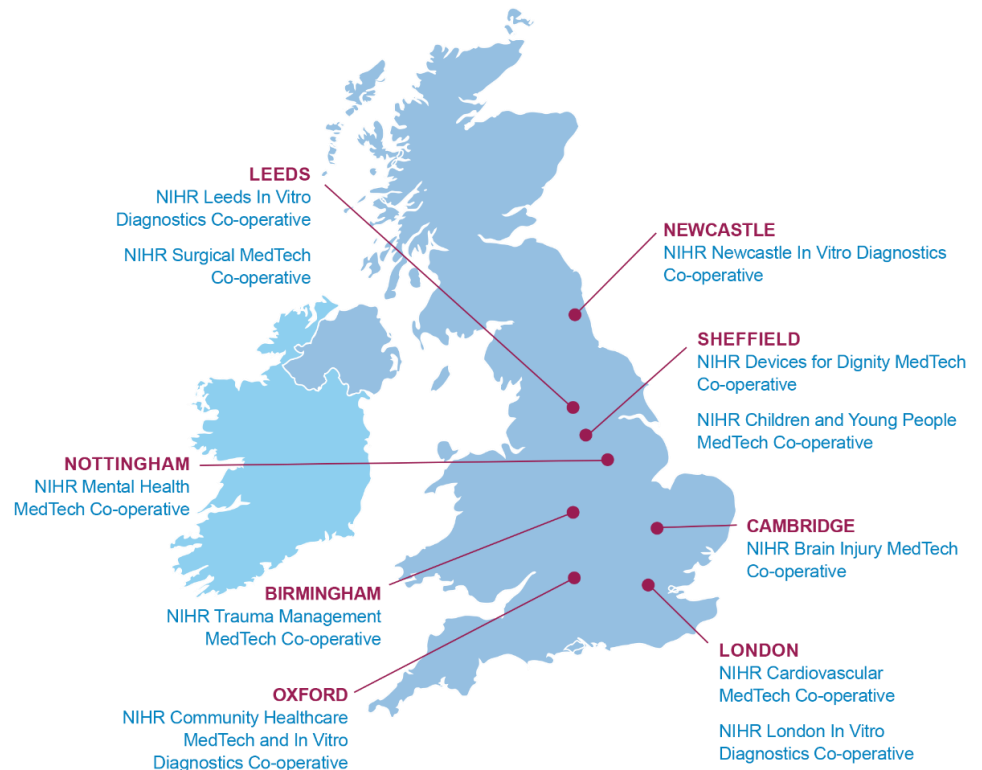
# Introductions



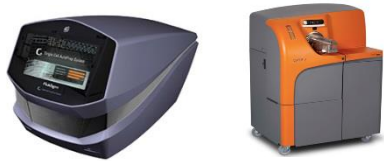
- The NIHR MIC
  - who are we and what we do?
- The evidence development pathway
- The agenda for today

# Who are we?

- 11 NIHR MICs across England established in January 2018, replacing the HTC and DEC
- Some MICs focus on the development of new medical technologies (MedTech)
- Other MICs help to generate evidence and evaluate in vitro diagnostic tests



# Diagnostics North East



MRC/NU Single Cell Unit  
(NUSCU)









External Assessment Centre

# The Newcastle MIC Team

Senior Methodologists		Director	Deputy Director	STP Clinical Bioinformatics	R&D Study Manager	Project Manager
						
Dr. Joy Allen	Dr. Sara Graziadio	Prof. John Simpson	Dr. Andrew Sims	Rachel O'Leary	Dr. Rachel Dickinson	Anna Halstead

## Methodologists

					
Dr. Alison Bray	Dr. Clare Lendrem	Dr. William Jones	Dr. Jana Suklan	Helen Elliot	Amanda Winter

# Research Themes



Infectious diseases led  
by Ashley Price  
(e.g. Sepsis, Influenza)



Ageing and long-term  
conditions led by  
James Frith  
(e.g. Stroke, COPD)



Personalised medicine  
led by Nick Reynolds  
(e.g. Familial  
hypercholesterolemia,  
breast cancer)

For further information:

0191 208 3709 | [nihr.newcastle.mic@newcastle.ac.uk](mailto:nihr.newcastle.mic@newcastle.ac.uk) | [www.newcastle.mic.nihr.ac.uk](http://www.newcastle.mic.nihr.ac.uk) |  @NIHR\_NCL\_MIC

# The evidence development pathway





# An overview

## IVD developers

- Academia
- Industry
- NHS

**Discovery or  
Invention**

**Early assessment of  
potential value**

## Stakeholders

- Patients
- Commissioners
- Healthcare professionals
- Clinical networks

**R&D laboratory  
performance**

**Analytic  
validity**

- Accuracy
- Reproducibility
- Safety

**Prototype**

**Clinical  
performance**

**Diagnostic  
accuracy**

- Sensitivity
- Specificity
- Predictive values

**Prototype**

**Demonstration of patient  
outcomes**

**Clinical utility**

- Patient benefits
- Patient harms

**Final product**

**Actual value:  
Business case  
development**

- Patient outcomes
- Economic value
- Budget impact
- Feasibility of implementation

**Adoption &  
implementation**

## Adopters

- System (DH)
- NHS Commissioners
- NHS Providers

Stakeholder  
engagement

Barriers and facilitators to adoption

Usability and human factors

Health  
economics

Care pathway analysis

Headroom analysis

Early economic modelling

Full economic assessment

Value of information analysis

# Agenda

13:00 - 13:15 Introduction to the day and to the evidence development pathway

*Delivered by Sara Graziadio (MIC)*

13:15 - 13:50 Defining the value propositions: care pathway analysis

*Delivered by Will Jones (MIC)*

13:50 – 14:30 Statistical approaches to evaluating diagnostic tests

*Delivered by Kevin Wilson (School of Mathematics, Statistics and Physics) and Clare Lendrem (MIC)*

14:30 - 15:10 Health economic evaluations in diagnostics

*Delivered by Eoin Moloney and Dimitrios Tzelis (Institute of Health and Society, Newcastle University)*

15:10 - 15:30 Coffee break

15:30 - 16:10 Systematic literature reviews and evidence synthesis

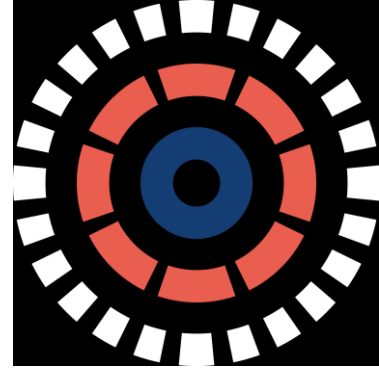
*Delivered by Lynn Barron-Millar and Patience Kunonga (Institute of Health and Society)*

16:10 – 16:50 Clinical studies: from funded application to study closure

*Delivered by Lisa Shaw (Stroke Research Group, Newcastle University)*

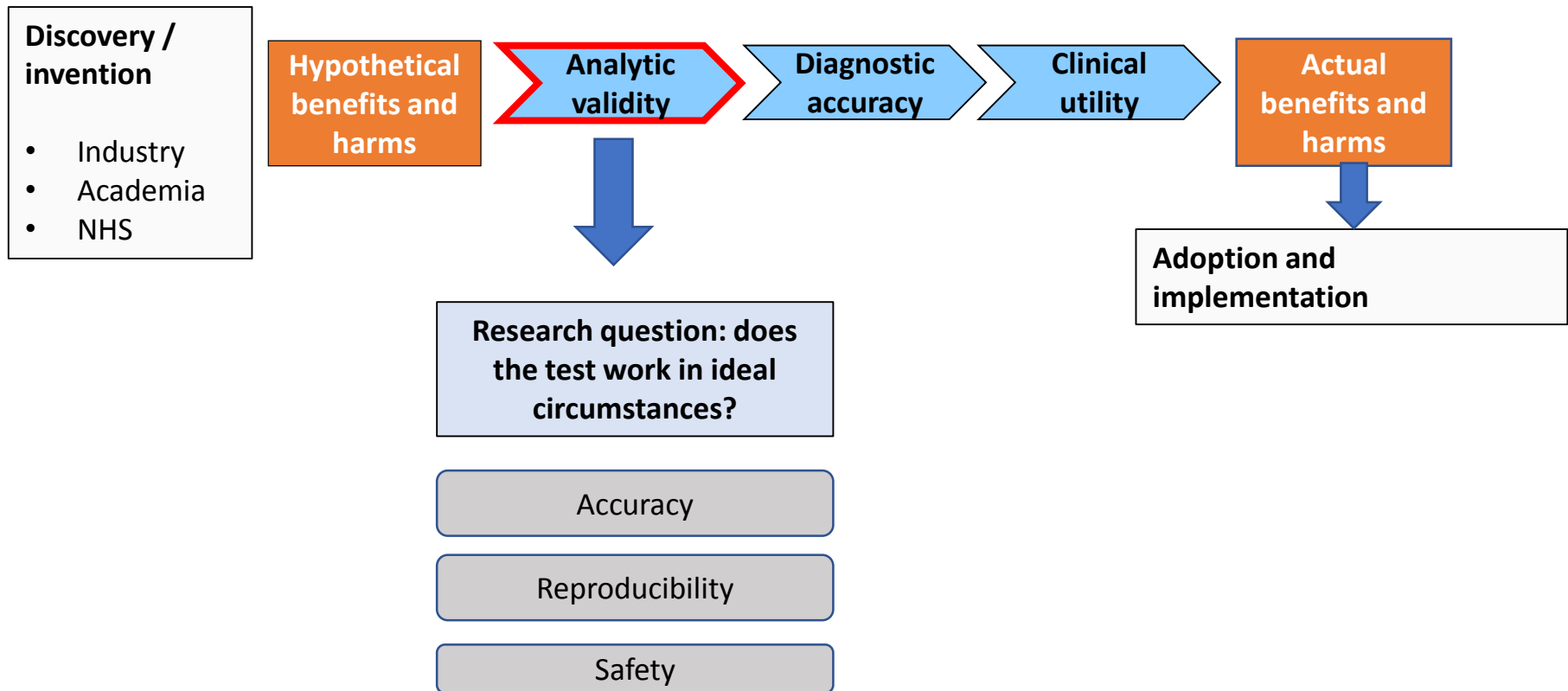
16:50 - 17:00 Conclusions

17:00 - 17:30 Drinks and networking

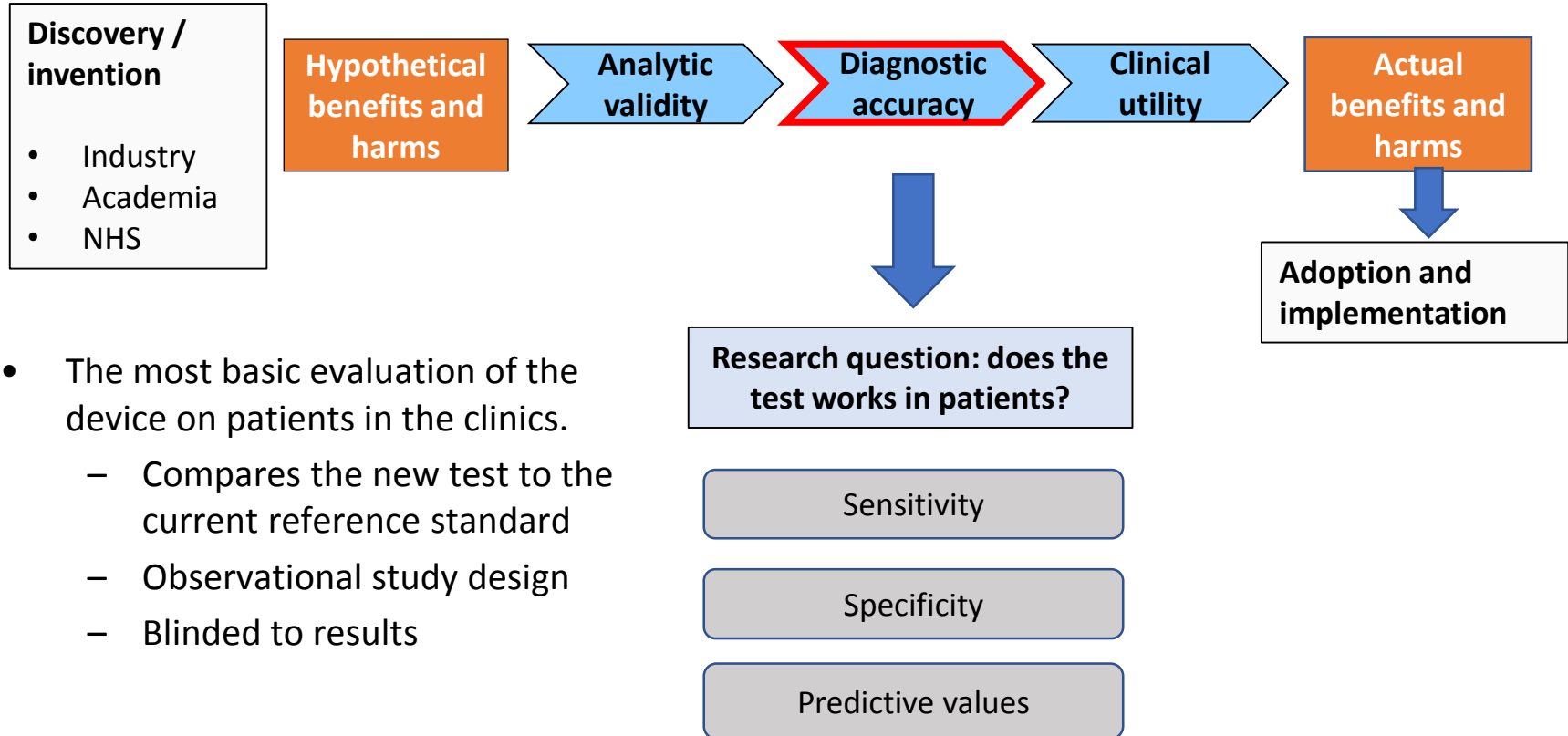


Enjoy the day!

# Analytic validity

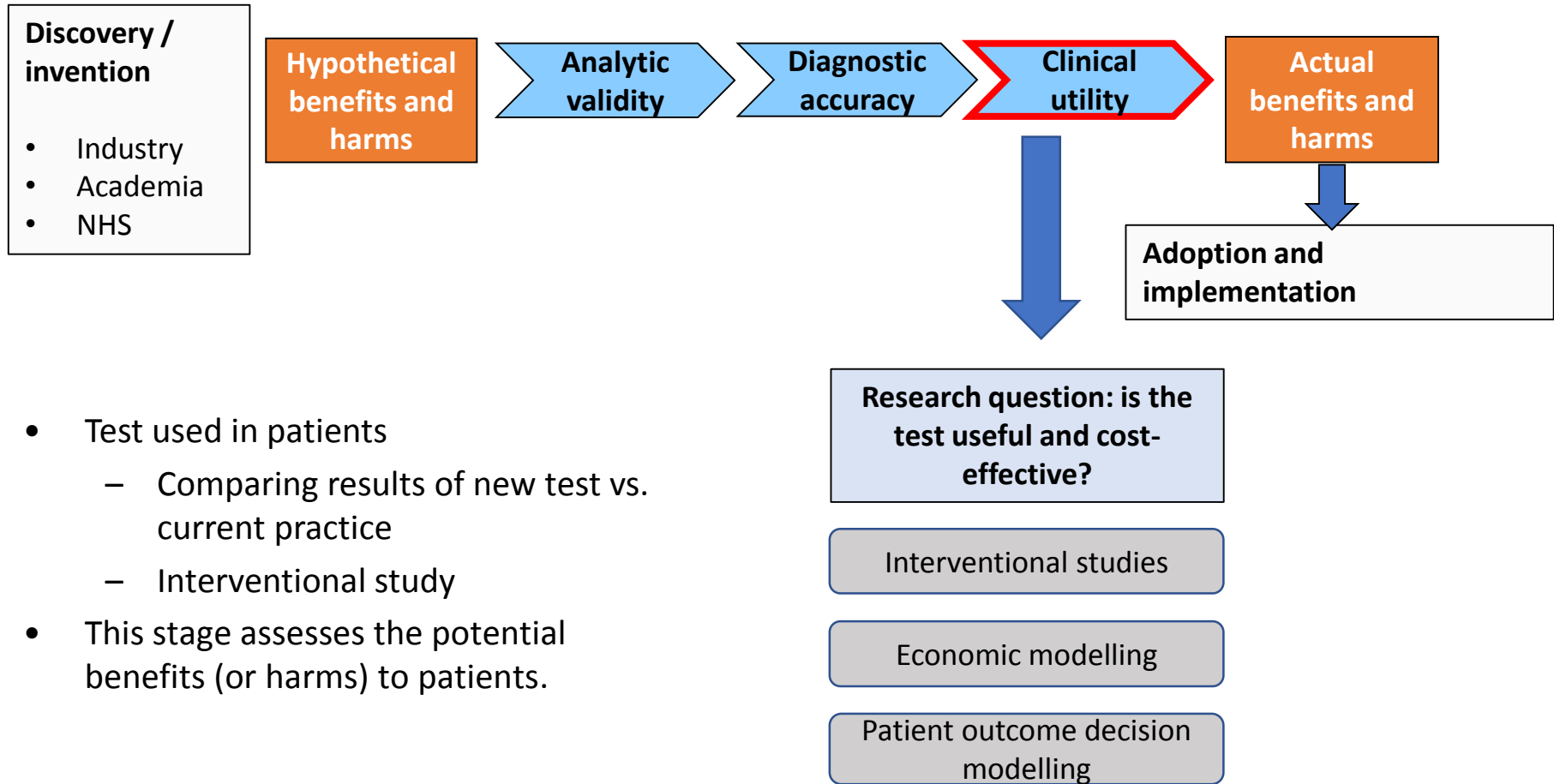


# Diagnostic accuracy



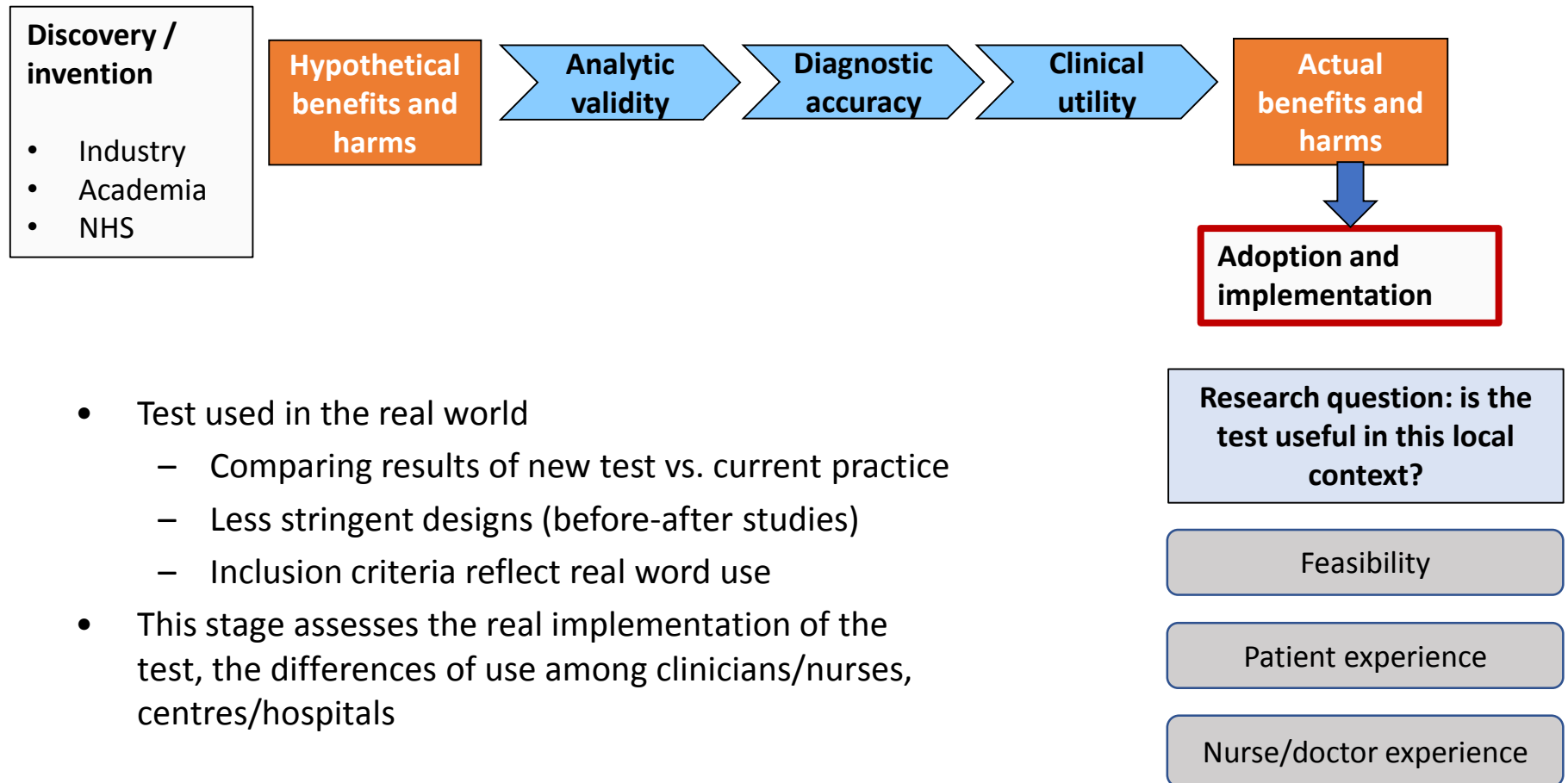
- The most basic evaluation of the device on patients in the clinics.
  - Compares the new test to the current reference standard
  - Observational study design
  - Blinded to results

# Clinical utility



- Test used in patients
  - Comparing results of new test vs. current practice
  - Interventional study
- This stage assesses the potential benefits (or harms) to patients.

# Adoption and implementation studies



# Adoption studies

