Introduction and Overview

Michael Messenger, Deputy Director

A partnership between the NHS, patients, academia, industry and charities
DEC Leeds: Scope & Skills

NIHR Applied Biomarkers Program
NIHR BRU
NIHR HTC

Renal
Liver
Musculoskeletal
Colorectal

Core Generic Biomarker Research Skills
- Assay Validation
- Clinical Biochemistry
- Study/Trial Design
- Quality Assurance
- Health Economics
- Clinical Informatics
- Biobanking
- PPI

Delivering Research in Primary and Secondary Care

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

- **Study Design** (Altman & Gregory)
- **Health Economics** (McCabe & P. Hall)
- **Health Informatics** (Jones and G. Hall)

PPM and SystmOne
DEC Leeds: Evidence Generation

Stage 1
Early modelling & prioritisation

Stage 2
Qualify Analytical validity

Stage 3
Qualify Clinical validity

Stage 4
Clinical utility and cost-effectiveness

Stage 5
Disseminate outputs

Clinical expertise and resources
Research sites, biobank samples & data, databases, registries

Methodological expertise and resources
Pathway & economic modelling, evidence synthesis, clinical informatics

Test developers
- Industry
- Academia
- NHS

Stakeholders
- Patient & Public
- Commissioners
- NHS / NIHR
- Trade associations
- Charities
- Regulators

Patient benefit

Economic value

- * Strategic decision making points
DEC Leeds: Evidence Generation

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**Patient benefit**

**Economic value**
Early modelling

Early diagnosis

Risk stratification

Treatment benefit prediction

Monitoring

Hospital admission

Acute disease diagnosed

Treatment initiation

Disease response

Hospital discharge

Rehabilitation/recovery

Chronic disease relapse

Late side-effects

Death
DEC Leeds: Evidence Generation

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**Economic value**
Qualify Analytical Validity

- Surplus diagnostic samples
- Evaluate influence of pre-analytical factors
- Method validation
- Method comparison
- External quality assessment
DEC Leeds: Evidence Generation

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Patient benefit
Economic value
Qualify Clinical Validity

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

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-* Strategic decision making points
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 Leeds:

- 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
• The Diagnostic Evidence Co-operative Leeds is funded by the National Institute for Health Research and is a partnership between the Leeds Teaching Hospitals Trust and the Universities of Alberta, Edinburgh, Leeds, Oxford, Southampton and University College London.

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