

Evidence to support the adoption of new biomarkers

3-DAY DIAGNOSTICS COURSE

22nd – 24th September 2014 | Queen's College, Oxford
www.oxford.dec.nihr.ac.uk

About the course:

The NIHR Diagnostic Evidence Cooperative (DEC) Oxford 3-day course on diagnostic test development, evaluation and regulation.

During these three days, you will be provided with the latest information on:

- **What evidence is needed to obtain regulatory approval.**
- **How NICE evaluates new diagnostic technology.**
- **How to collect evidence to support adoption in routine clinical practice.**

In addition, we will teach you about different study designs including quality assessment, and how to facilitate uptake in routine clinical practice.

The course combines talks with hands-on activities.

To stimulate interactive discussions and maximise the learning experience, the number of places for this course are limited.

Registration:

Register online via the [University of Oxford website](http://www.oxford.dec.nihr.ac.uk)

<http://bit.ly/decoxebd>

Speakers include:

Professor Chris Price, Visiting Professor in Clinical Biochemistry, University of Oxford.

Dr Ann Van den Bruel, Director of the NIHR Diagnostic Evidence Cooperative, Nuffield Department of Primary Care Health Sciences, University of Oxford.

Professor Carl Heneghan, Director of the Centre for Evidence-Based Medicine, Nuffield Department of Primary Care Health Sciences, University of Oxford.

Nia Roberts, Information Specialist, Boodlian Libraries, University of Oxford.

Stephen Lee, Biosciences Team Manager. Medicines and Healthcare products Regulatory Agency.

Dr Grace Jennings, NICE Scientific Advice.

Dr Annette Plüddemann, Director: Diagnostic Horizon Scan Programme, Nuffield Department of Primary Care Health Sciences, University of Oxford.

Dr Beth Shinkins, Research Fellow, Nuffield Department of Primary Care Health Sciences, University of Oxford.

Dr Antonis Kousoulis, Academic Research Liaison, Clinical Practice Research Datalink, Department of Health.

Ravi Chana, Business Development Manager, Office for Clinical Research Infrastructure (NOCRI).

Dr Jane Wolstenholme, Senior Researcher, Nuffield Department of Population Health, University of Oxford.

Dr Caroline Jones, Senior Researcher, Nuffield Department of Primary Care Health Sciences, University of Oxford.

This course is aimed at all professionals working on diagnostic tests, including those working in industry, academia, funding and regulation



NUFFIELD DEPARTMENT OF
PRIMARY CARE
HEALTH SCIENCES

Programme

Day 1: Monday 22nd September

- 09.00 – 09.40 Registration
- 09.40 – 10.00 Welcome
- 10.00 – 11.00 **Tests as part of a clinical pathway**
- 11.00 – 11.30 Coffee break
- 11.30 – 12.30 **Aligning research and development with clinical needs**
- 12.30 – 13.30 Lunch
- 13.30 – 14.30 **Different forms of evidence for different types of questions**
- 14.30 – 15.00 Coffee break
- 15.00 – 16.30 **Workshop: Searching for existing evidence to support regulatory approval and other purposes**

Day 2: Tuesday 23rd September

- 09.00 – 10.30 **Evidence for regulatory purposes: CE marking, European IVD Directive and FDA approval processes**
- 10.30 – 11.00 Coffee break
- 11.00 – 12.30 **Evidence for implementation in routine clinical practice – NICE evaluations**
- 12.30 – 13.30 Lunch
- 13.30 – 15.00 **Workshop: How to avoid low quality studies**
- 15.00 – 15.30 Coffee break
- 15.30 – 16.30 **Basic stats in diagnostic studies**
- In the evening join us for the course dinner and interactive discussion: Building evidence for new tests with the Clinical Practice Research Datalink (CPRD).**

Day 3: Wednesday 24th September

- 09.00 – 10.30 **Funding for diagnostic test development/opportunities for collaboration with academia**
- 10.30 – 10.45 Coffee break
- 10.45 – 11.45 **Economic modelling to inform the development of new tests**
- 11.45 – 12.45 **Using evidence to support the business case: the route to adoption**
- 12.45 – 14.00 Lunch
- 14.00 – 15.30 **Interactive discussion: Facilitators and barriers for uptake in routine clinical practice**
- 15.00 – 16.00 **Closing remarks**