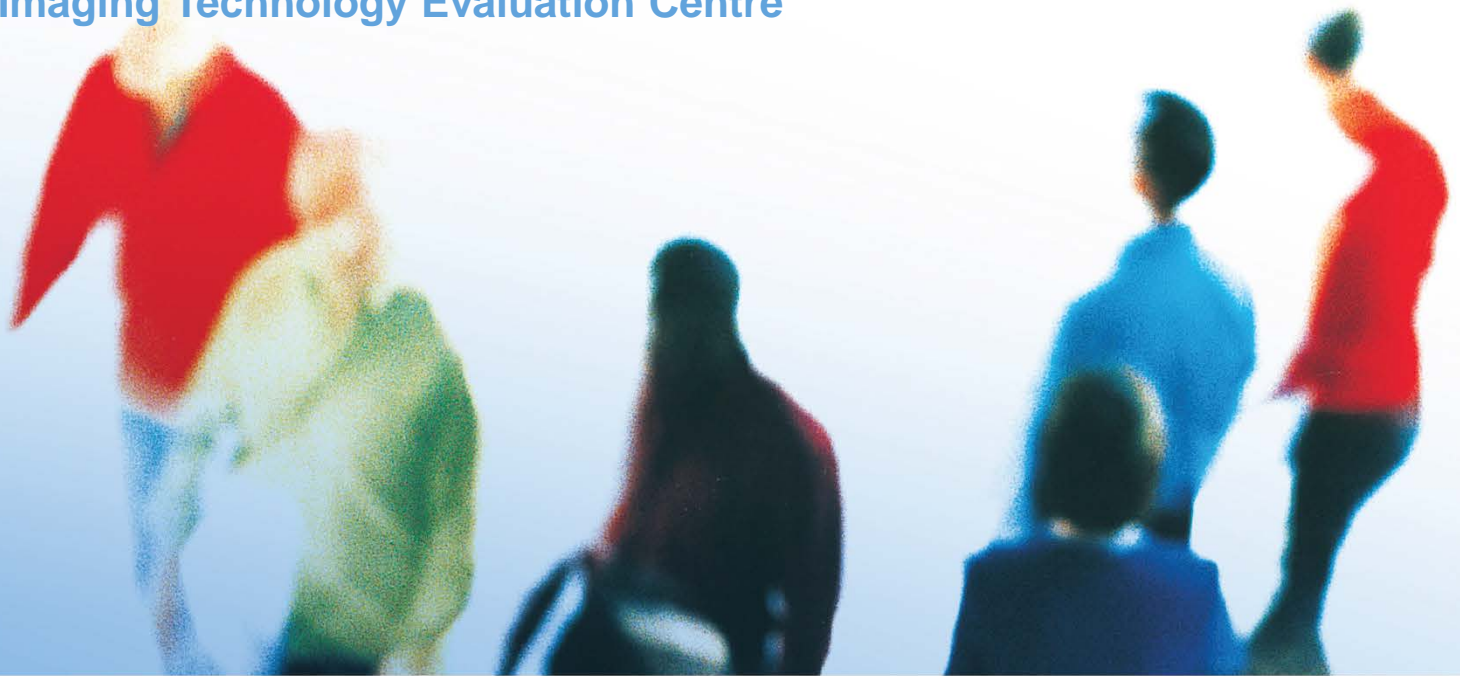


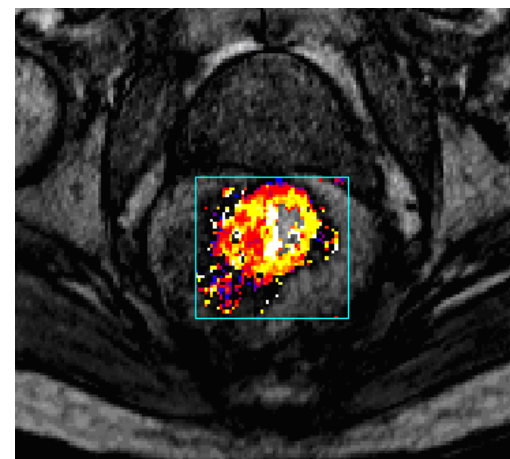
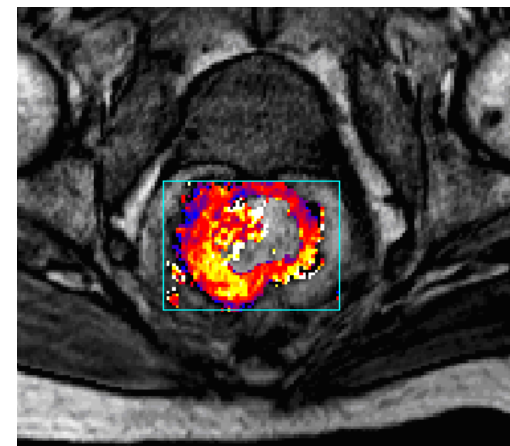
Imaging technology evaluation for NICE: a physicist's perspective

Professor Stephen Keevil, Joint Director,
KITEC: King's Imaging Technology Evaluation Centre





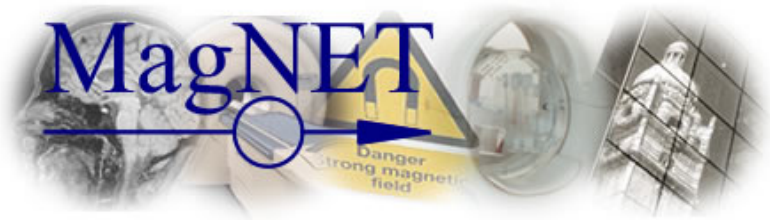
- Imaging is no longer a purely diagnostic technique: it is increasingly important in treatment planning, guidance and assessment
- Imaging biomarkers have the potential to characterise individual patients, enabling personalised medicine
 - Improved quality of care through better patient selection
 - Reduced costs through identifying non-beneficial treatments
- Imaging makes increasing demands on capital and revenue budgets
 - Rapid development requires rapid adoption
 - But the evidence base is often poor
- Needs an integrated approach involving manufacturers, technical experts and clinical end users



GCAT

FAXIL

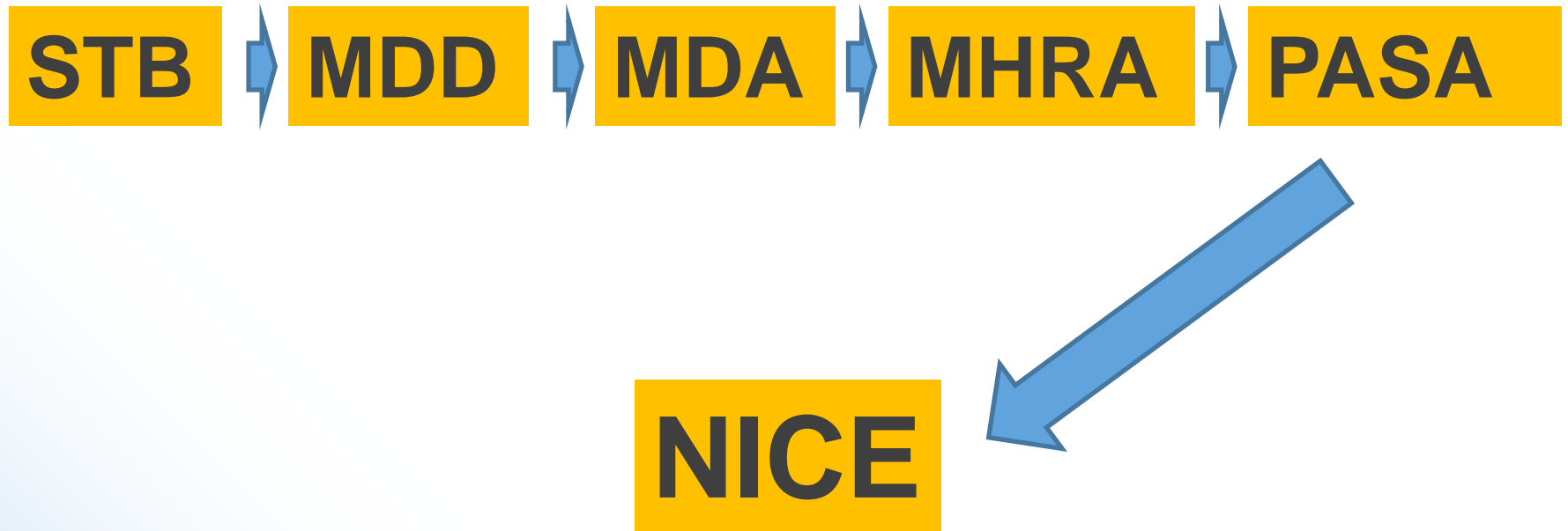
ImPACT



PACSnet

UEEP

KCARE



CCAT

FAXIL



NICE is seeking to commission four external assessment centres (EACs) to provide a service to support the Evaluation Pathway and its related NICE programmes (see section 2.2). The envisaged four centres will each provide a comprehensive range of services as set out at section 4, but are required to have the following technical subspecialisation, with the associated knowledge and expertise:

- Medical devices (two centres)
- Imaging technologies (one centre)
- In vitro diagnostic tests (one centre).

KCARE

- Assessment reports
- Facilitating collaborative research into clinical and cost utility
- Specification, compilation and analysis of databases and registers
- Systematic reviews and meta-analysis
- Technical evaluation to advise on effective use

- Much broader than previous assessment centres: requires a multidisciplinary approach
- An idea task for an Academic Health Science Centre!



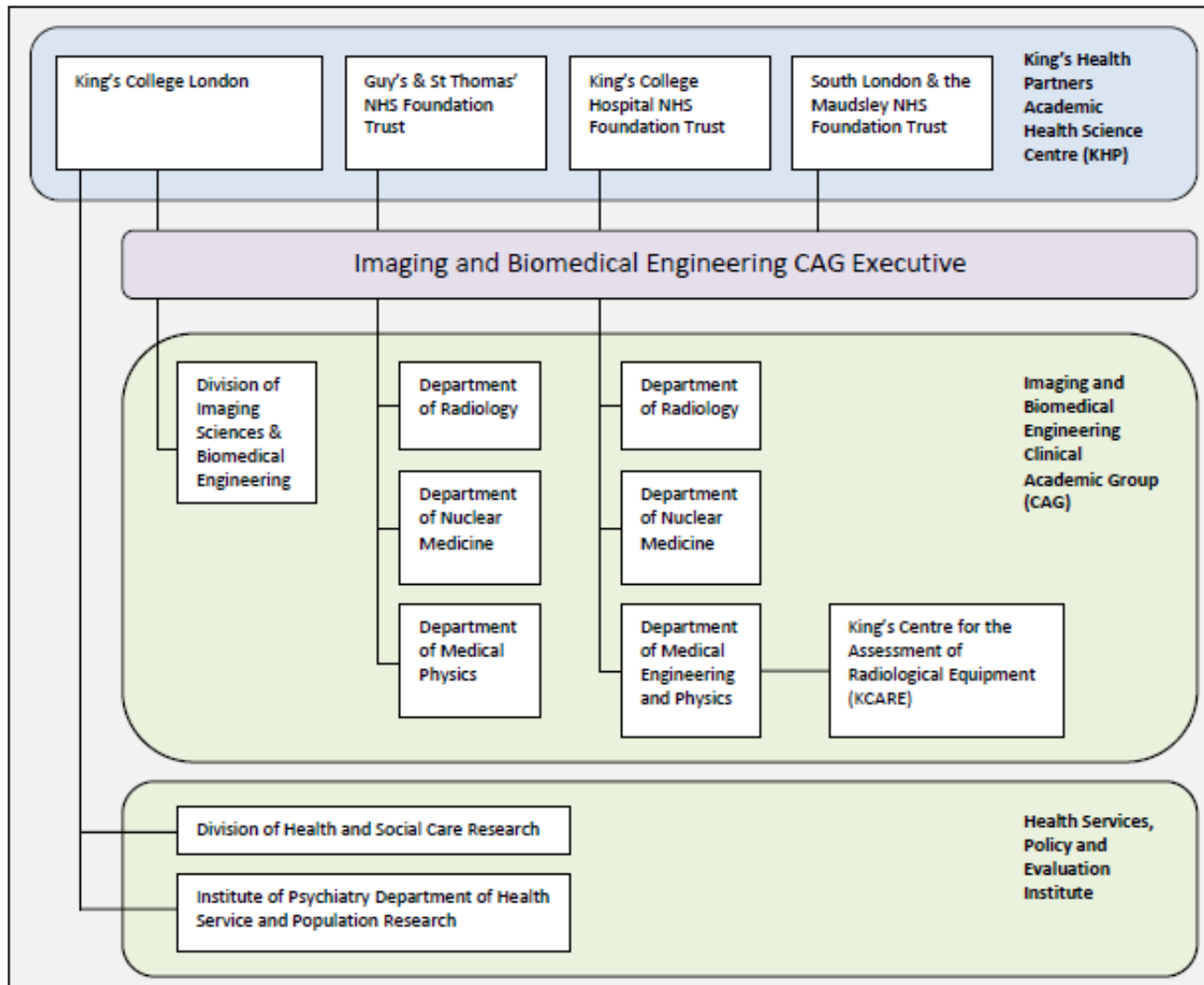
King's Health Partners Tender for NICE External Assessment Centre Four – Imaging Technologies

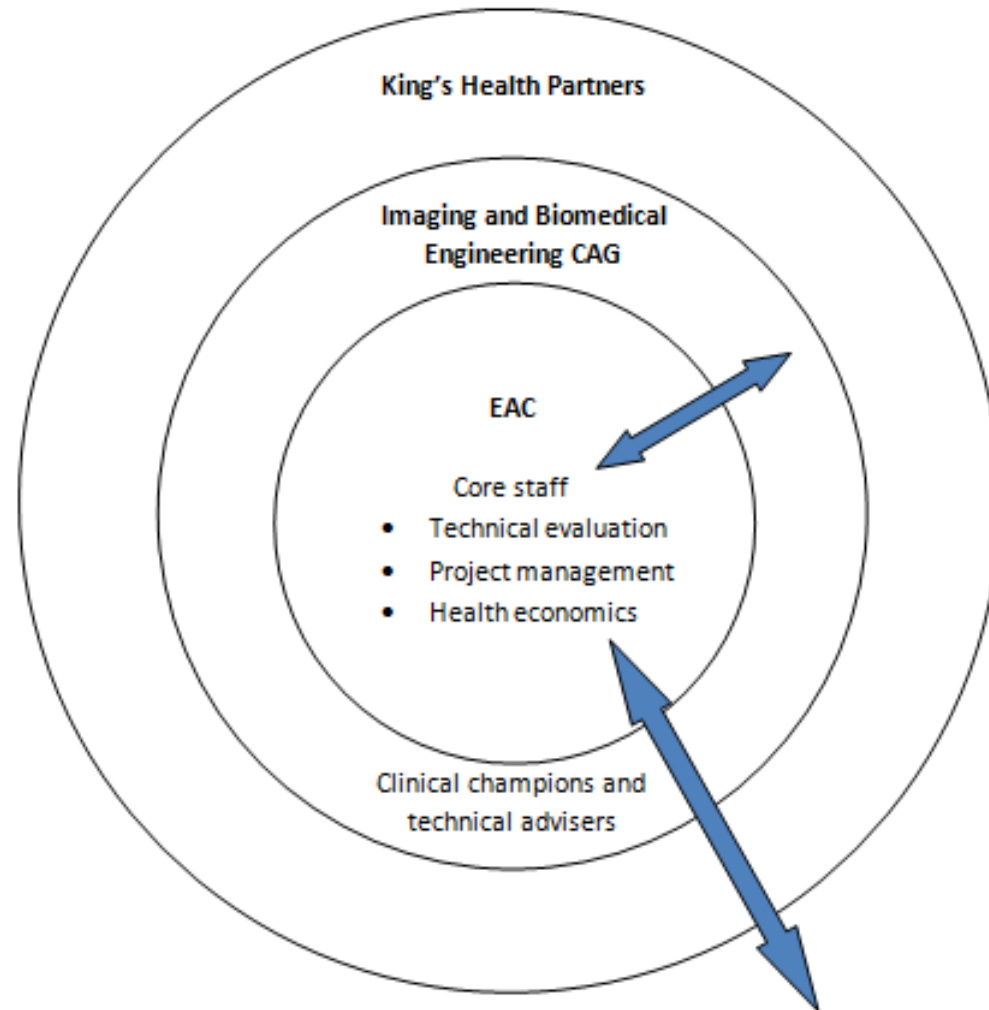
Executive Summary

Background and context

Imaging continues to place high demands on hospital and health system capital and revenue budgets due to high equipment costs, rapid technological change and the need to recruit, train and retain highly skilled staff. Over the last few decades, advances in medical imaging have provided new measures for characterizing individual patients, resulting in the growing application of imaging in a variety of care pathways. Furthermore, the role of imaging has significantly changed from being purely diagnostic towards becoming a tool for image-guided surgical and therapeutic intervention. Today, imaging is increasingly used to assess the effects of treatment and to predict outcome. These imaging biomarkers are potentially of high importance in the development of new treatments (e.g. drugs, medical devices) and the selection of appropriate treatments for individual patients (personalised medicine). Personalisation of treatment has the potential to improve the quality of care by refining patient selection and characterisation and delivering better clinical outcomes. It will hopefully also lead to substantial cost reduction by identifying treatments that have little or no benefit for individual patients. But it is important that new applications of imaging are evidence-based and cost-effective. At present, new imaging technology is often adopted

Relationship between the partners

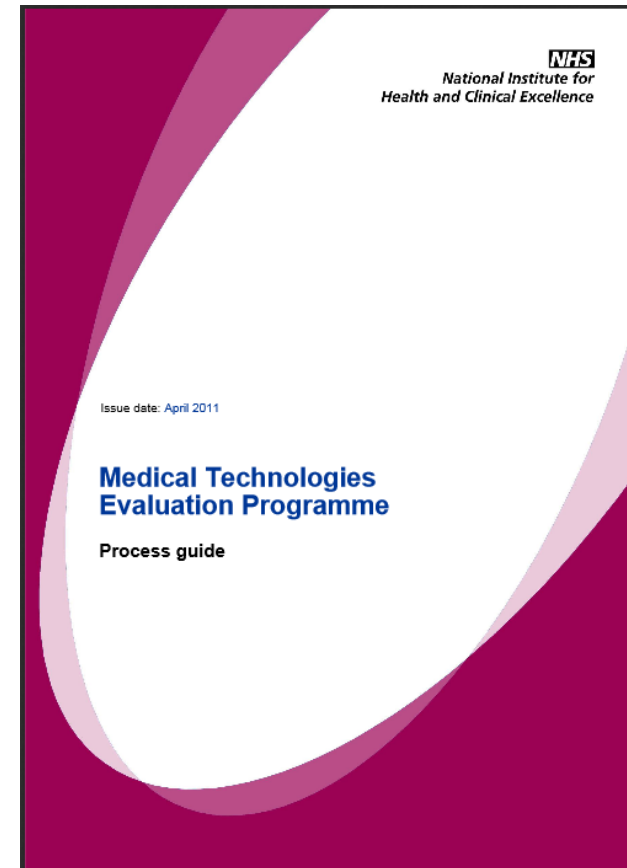




- Tender submitted 9th December 2010
- Final round presentations scheduled for 22nd December 2010, postponed due to snow
- January 2011- March 2012 negotiations!
- Contract awarded March 2012
- So 2 years of 3 year term remaining
- Work slow to ramp up, very busy since Christmas 2012



- To promote faster uptake of new medical technologies in the NHS
- To encourage collaborative research, in both industry and the NHS, to generate evidence on the clinical utility and/or healthcare system benefits of selected technologies



- Technology is a medical device (defined in EU Directive 93/42/EEC, as amended)
- Technology is new or innovative technology
- Technology has a CE mark, or this is expected within 12 months
- Technology is available in the NHS, or manufacturer plans to launch it in the NHS



- Technology notified by manufacturer / sponsor
- NICE consults with Expert Advisers
- Medical Technologies Advisory Committee selects suitable technologies
 - September MTAC: 2/6 technologies selected
 - Reasons for rejection: inadequate clinical evidence, inadequate economic evidence, not unique...
- Routed to MTEP if technology:
 - is likely to be cost saving or cost neutral
 - can be evaluated as a single technology
 - can be evaluated on a short timescale
- Or can be routed to other programmes



- Project allocated to an External Assessment Centre (EAC)
- NICE prepares and consults on scope, defining disease(s), patients and technology covered by the assessment, outcomes, relevant comparators
- Manufacturer submission of clinical evidence (2 weeks)
- Manufacturer submission of economic evidence (6 weeks)
- EAC assessment report submitted (10 weeks)
- EAC presents at MTAC meeting. MTAC produces draft recommendations (c15 weeks)
- Final guidance issued following consultation (c32 weeks)

- c100 pages
- c100 person-days of work
- Critique of clinical evidence: search strategy, study selection
- Critique of study methodology and sponsor's analysis and synthesis
- Additional work on clinical evidence
- Critique of economic evidence: search strategy, study selection
- Critique of cost model
- Additional work on economic evidence

KING'S
College
LONDON

Assessment Report

**The geko™ electro-stimulation
device for venous
thromboembolism prophylaxis**

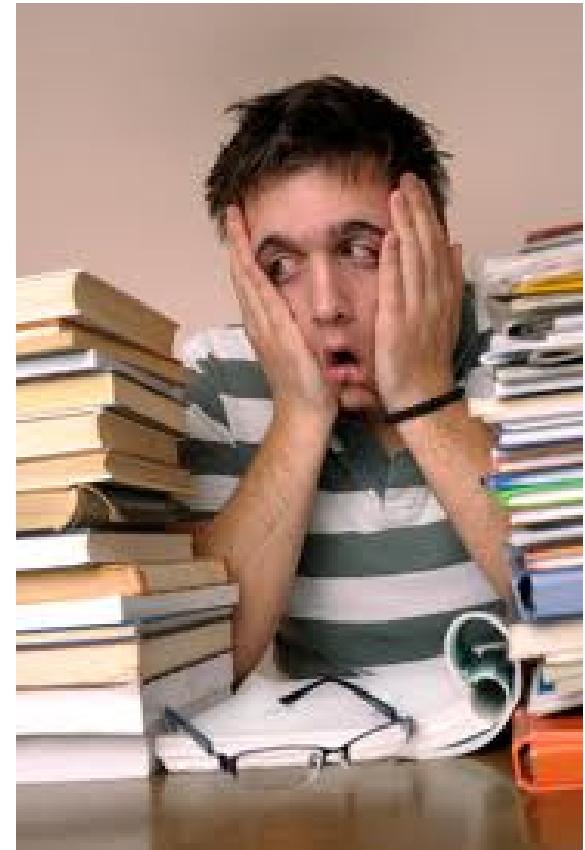
 KING'S HEALTH PARTNERS

KITEC - King's Imaging Technology Evaluation Centre
Department of Medical Engineering and Physics
King's College Hospital NHS Foundation Trust
Denmark Hill
London, SE5 9RS, UK
Phone: +44 (0) 203 299 1627
Fax: +44 (0) 203 299 3314



Certificate No. FS34209

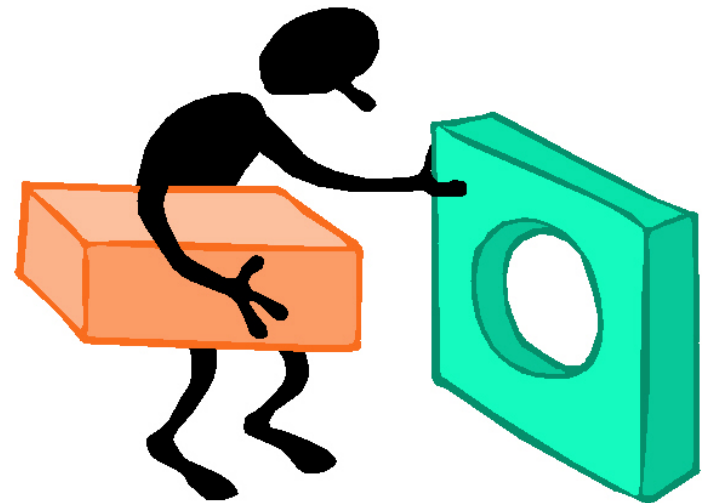
- Assessment report: 2 (neither imaging related!)
- Initial product assessment: 62
- Research facilitation: 4
- Establishment of registers: 1
- Technical advice / horizon scanning: 4
- Expressions of interest: 8
- Miscellaneous: 3



- Very few imaging devices are coming through the programme
 - New or novel 'single technologies' that reduce costs are rare
 - Incremental development by several companies in parallel: about methods, not manufacturers
 - The Diagnostics Assessment Programme (DAP) can consider (1) multiple technologies, (2) cost-effectiveness
 - There is little evidence of impact of imaging on patient outcomes
- We are being used as a generic assessment centre and a source of specialist advice on imaging



- Only 2 years left when the contract was signed: difficult to recruit good people to fixed term contracts
- Work can be complex, requiring significant senior level input
- Difficult to coordinate work of four different teams across three campuses
- Difficulties at NHS-university interface: finance, HR, IT...



- It's been challenging but interesting; we're keen to continue
- We and NICE have learned a lot from the process
- Current contract expires March 2014
- New call for tenders will be issued...

