National Institute for Health Research

The NIHR Health Technology Assessment Programme

Pushing and pulling the research community to address health care needs

Hywel Williams

Chair of the NIHR HTA Commissioning Board

Relevance for this meeting

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- Huge benefit for Nottingham campus
- Less as a funding source for international research
- Many aspects (strategy, structure, process) may be interesting to colleagues in Malaysia and China
- Health Technology Assessment International http://www.htai.org/ (Ministry of Health, Malaysia & Singapore)

What I am going to do:

NHS
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- Definitions – what is HTA?
- More about the NIHR Programmes
- More about the HTA process
- Features of successful proposals

The HTA Programme (1993)

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- The Health Technology Assessment programme produces independent research about the effectiveness of different healthcare treatments and tests for those who use, manage and provide care in the UK National Health Service.

- It identifies the most important questions that the NHS needs the answers to by consulting widely with these groups, and commissions the research it thinks is most important through different funding routes.

- Patient and public involvement (PPI) throughout

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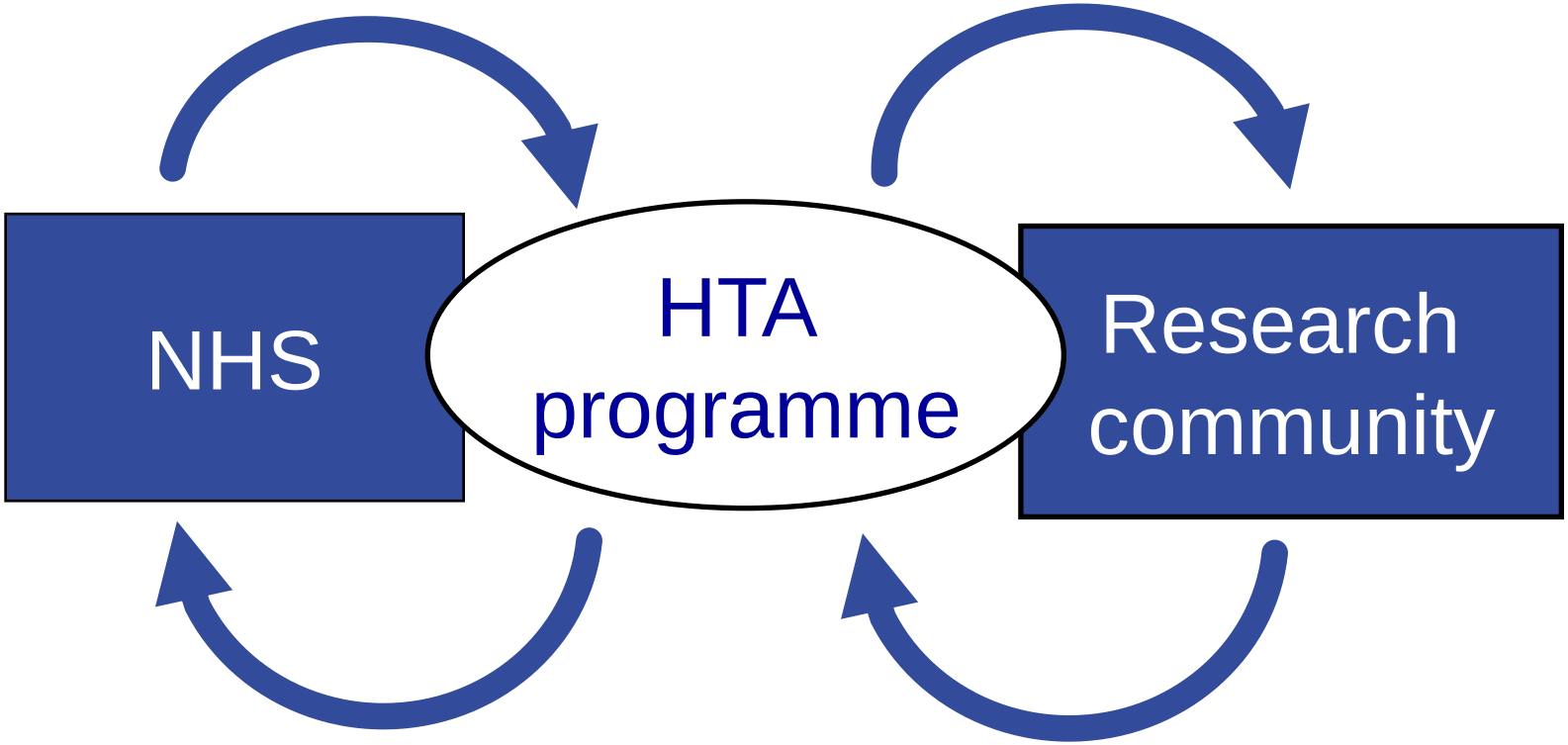

•ensuring that high quality information about the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, provide care in, make policy for and manage the NHS

What is “health technology”?

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- covers a range of methods such as systematic reviews, clinical trials, cohort studies, modelling studies to promote health, prevent and treat disease and improve rehabilitation and long term care including:
  - Drugs: such as antidepressants, contraceptives, antibiotics
  - Devices: such as pacemakers, dialysis machines, hearing aids
  - Procedures: eg surgical techniques, acupuncture, counselling
  - Settings of care: such as general practice, hospitals, care homes
  - Screening: for cancer, sexually transmitted diseases, stroke

Similar to CER in the US

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- Comparative effectiveness research (CER) is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in “real world” settings.

- The purpose of this research is to improve health outcomes by developing and disseminating evidence makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.

Source: Anne Trontell. AHRQ, April 2010
http://www.fda.gov/downloads/Drugs/NewsEvents/UCM209104.pdf

CER and HTA is NOT:

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- Solely about effectiveness
- Solely about cost-effectiveness
- Intended as regulatory or directive
- Restricted to randomized controlled trials
- Exclusionary of clinical judgment or the circumstances of the individual patient
- Aimed at limiting or restricting health services

CER in the US – massive new investment

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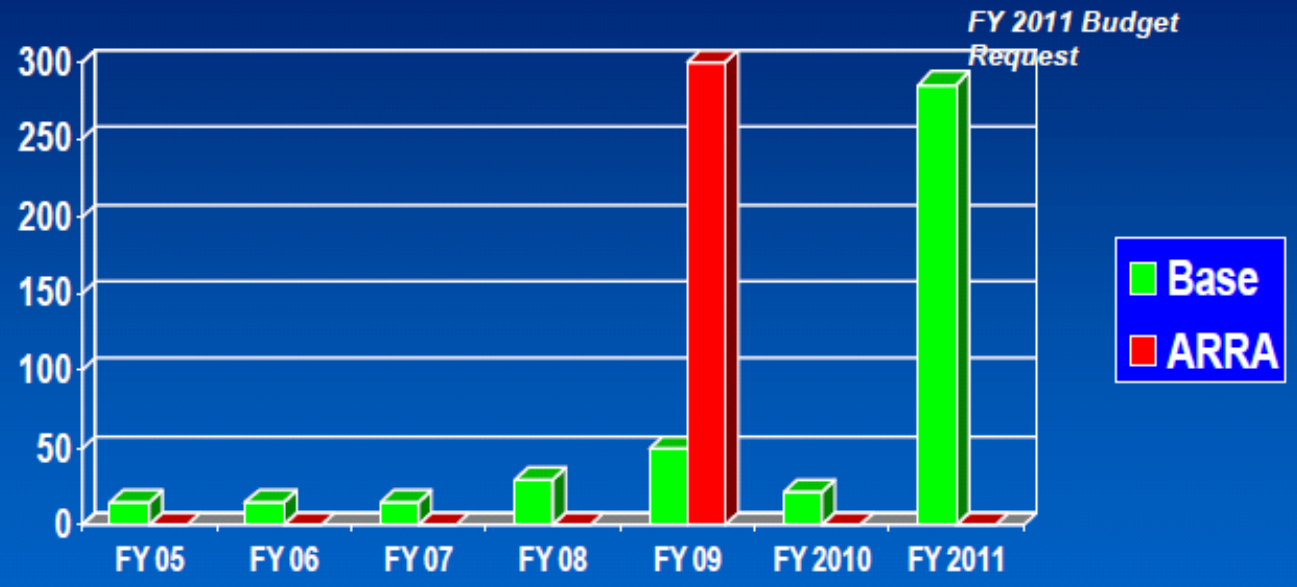
ARRA, the American Recovery and Reinvestment Act of 2009 included $1.1 billion for comparative effectiveness research:

- AHRQ: $300 million
- NIH: $400 million
- Secretary's Office of the Secretary: $400 million (allocated at the Secretary's discretion)

AHRQ Funding for Comparative Effectiveness ($ in millions)



President's proposed 2011 budget is $286 M for "patient-centered health research"

Back to the UK...

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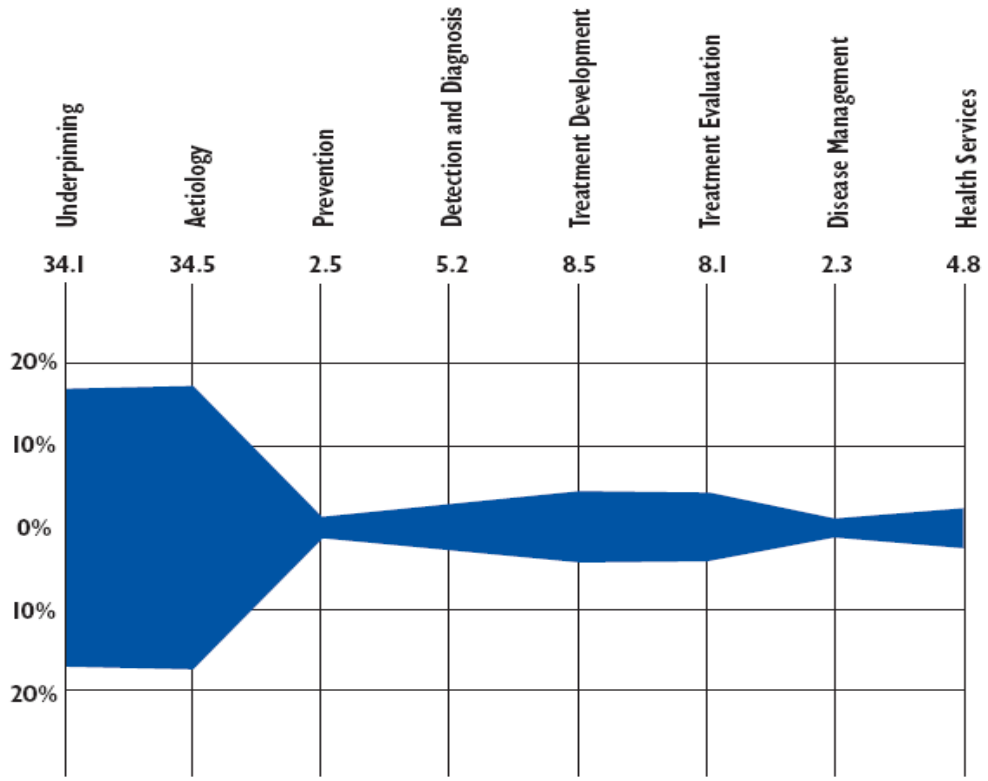

Combined MRC and DH spend
Research spend 2004/2005 - UKCRC analysis

Key issues that needed addressing

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- Decline in clinical research community
- Decline in infrastructure for clinical research
- Complex regulatory environment
- Need to recognise Industry R&D needs in the UK
- Not yet realising the Potential of a single National Health Service

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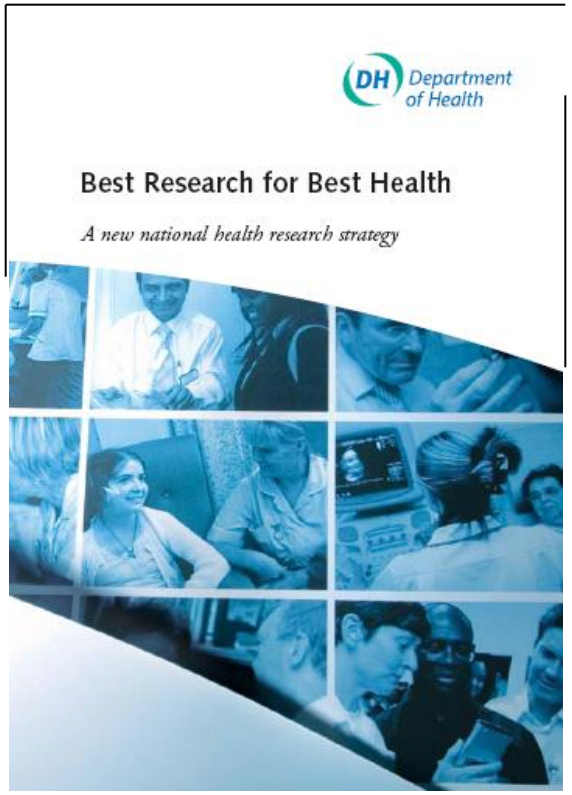
NHS R&D Strategy 2006

"To create a health research system in which the NHS supports **outstanding individuals**, working in **world-class facilities**, conducting **leading-edge research**, focused on the **needs of patients and the public"**



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Professor Dame Sally Davies

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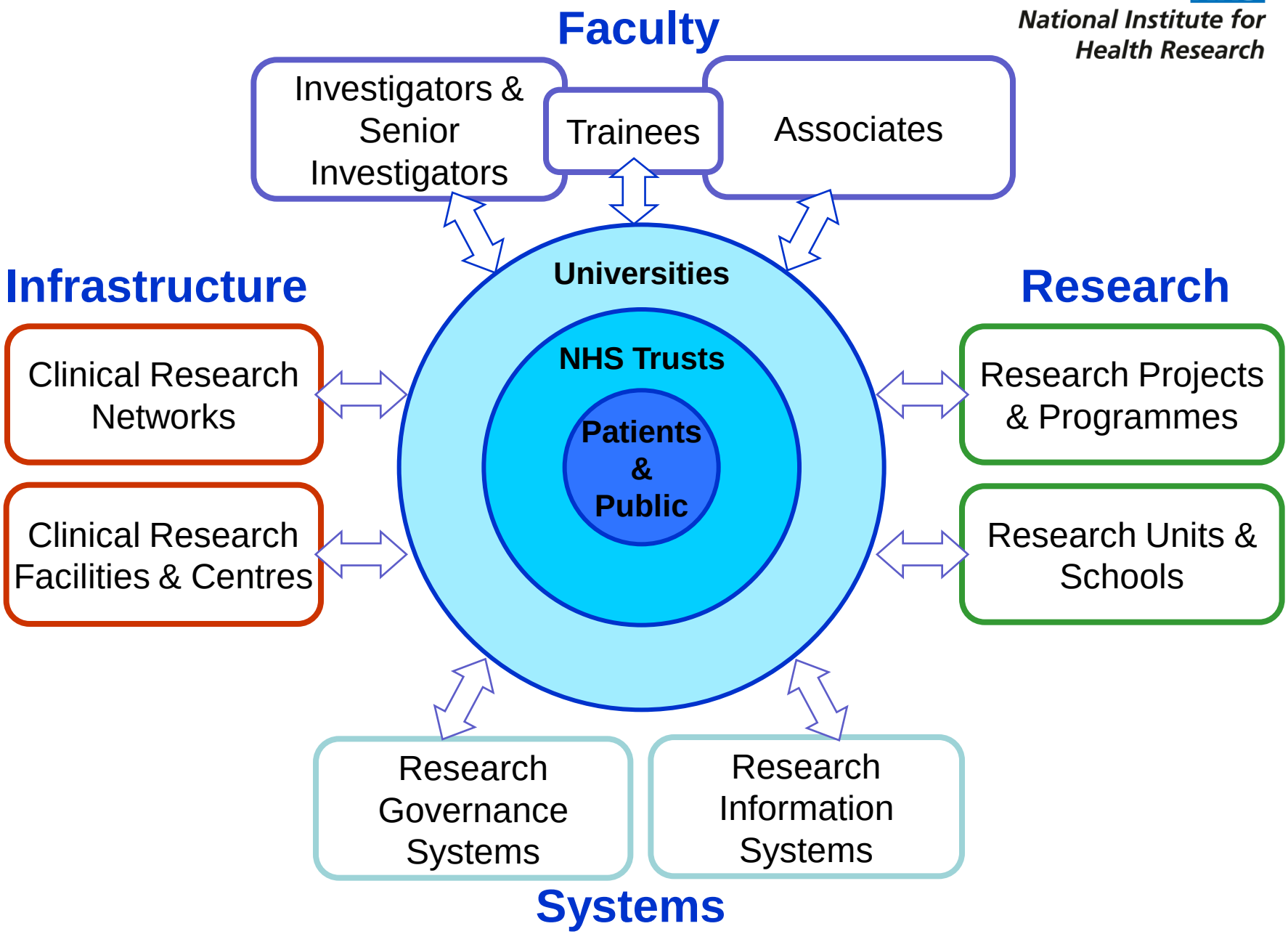

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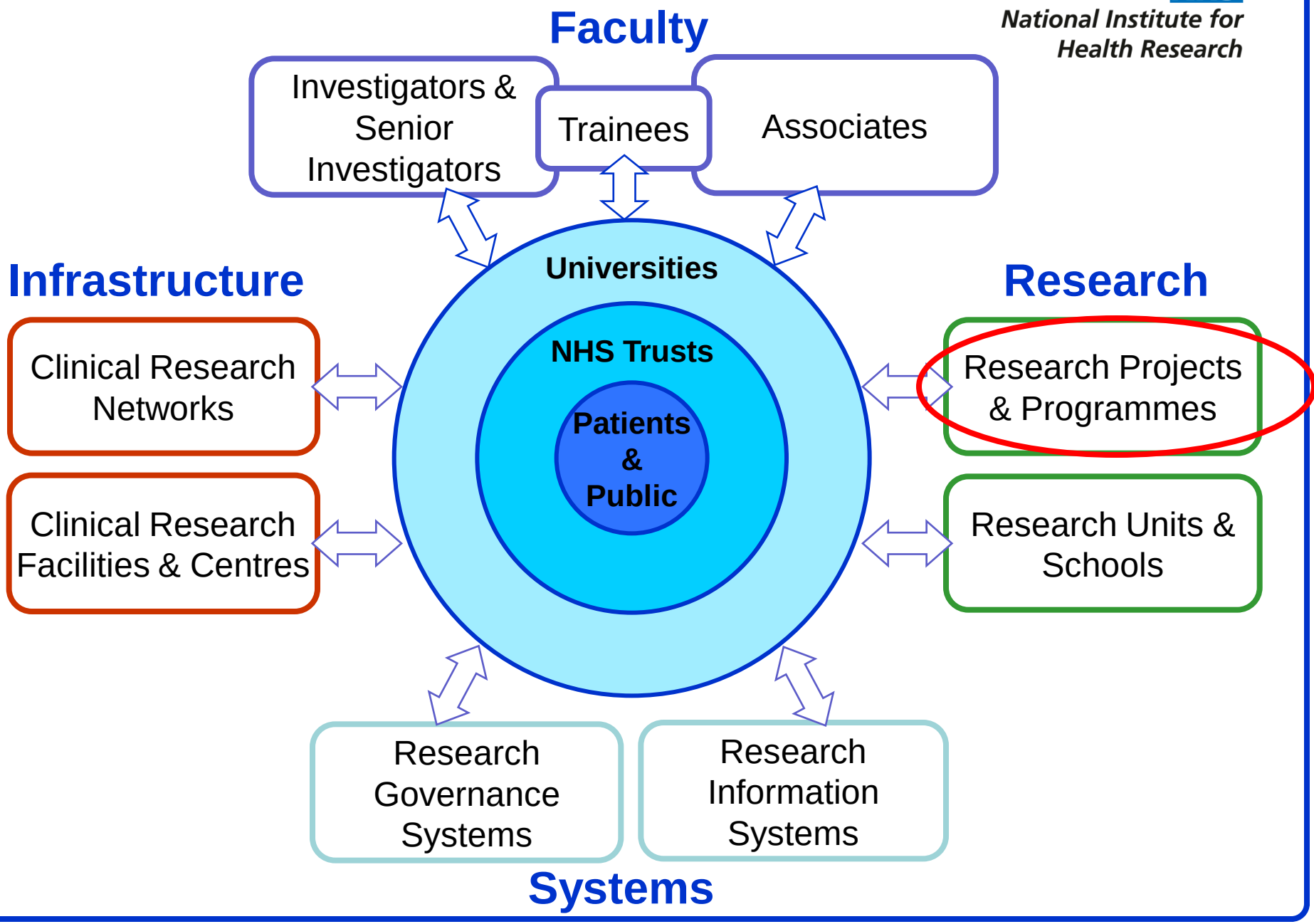

NIHR Evaluation, Trials and Studies (NETS) programmes

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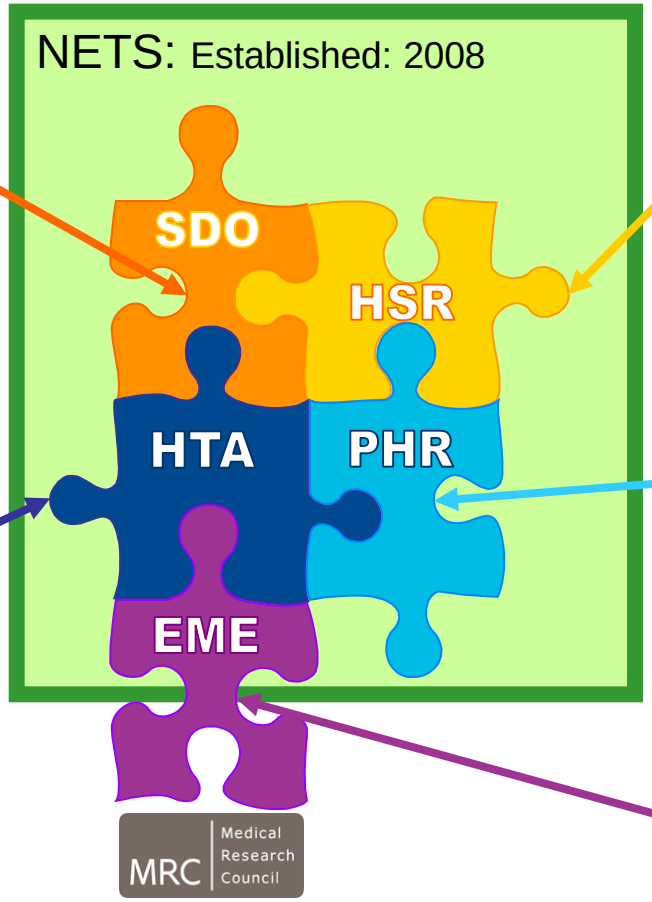
Service Delivery & Organisation

Established:
1999 (LSH&TM)
2009 (NETSCC)
Budget: £11m

Health Technology Assessment

Established: 1993

Budget: £88m



Health Services Research

Established: 2008

Budget: £5m

Public Health Research

Established: 2008

Budget: £10m

Efficacy and Mechanism Evaluation
Funded by the MRC
Managed by NIHR

Established: 2008
Budget: £15m

Budget figures are indicative of predicted annual spend in 2011/12

Efficacy and Mechanism Evaluation (EME) programme

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MRC Medical Research Council

- Remit

To support clinical trials and studies which:

  - add significantly to our understanding of biological or behavioural mechanisms and processes;
  - explore new scientific or clinical principles;
  - evaluate clinical efficacy of healthcare interventions (drugs, technology, diagnostics, procedures)

- Laboratory embedded in main study
- May include validated surrogate markers as indicators of outcome
- Mainly responsive mode “pull through”
- More recently – commissioned stream eg point of care

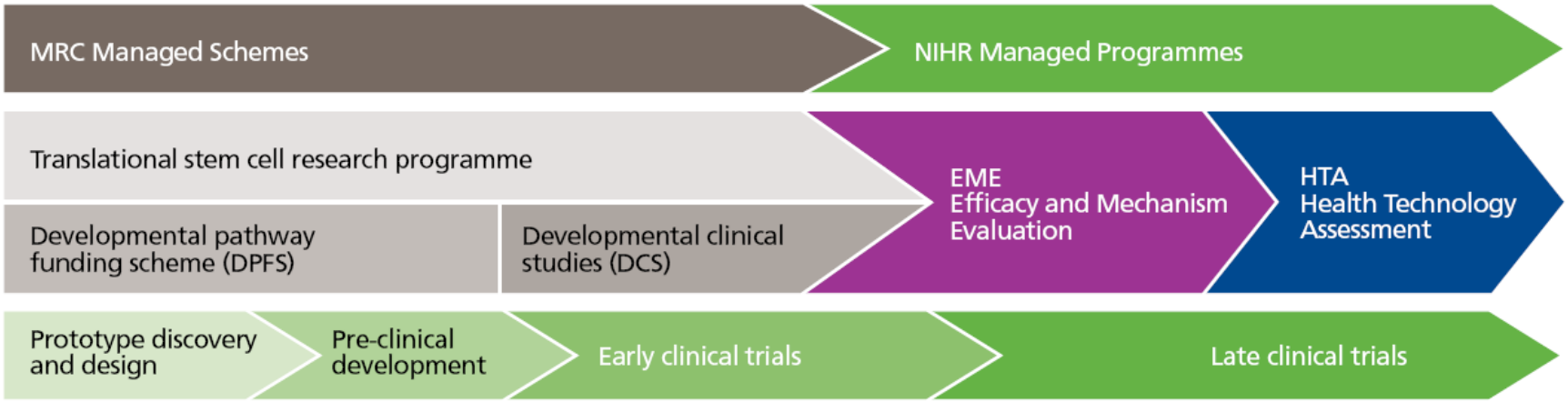
EME does not support:

- Incremental modifications
- Refinements of existing technologies

- Proof of concept
- Proof of mechanism in human
- Confidence in Effect

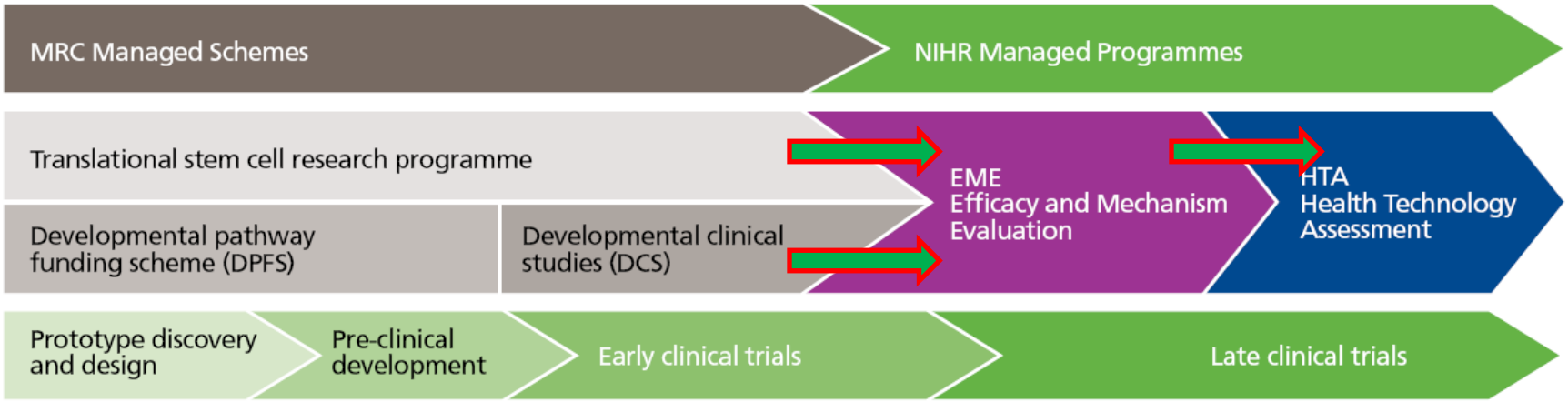
- Very early phase Clinical Trials (I, IIa)

The Managed Translational Pathway



The Managed Translational Pathway

Successful development?



"Pull through"

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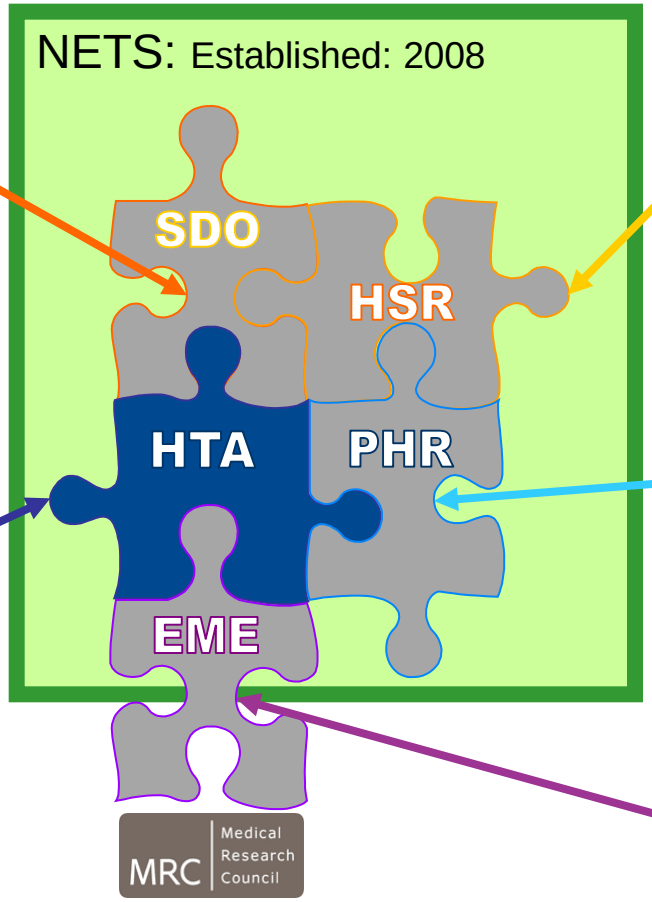

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Getting innovations into practice

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Does it work? Is it safe? Can it be done in the NHS?

What if it is done in the NHS?

Should it be done in the NHS - appraisal

Horizon-scanning

EME

HTA

SDO

Basic biomedical research

MRC, Various funders

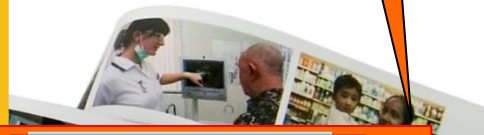
Translational research

MRC, NEAT

Safety and efficacy

Effectiveness and cost-effectiveness

General clinical use



Appraisal (NICE)

Specialist commissioning

Tasks for the HTA Programme

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- Identifying needs of NHS for research into technologies
  - What are the large and challenging problems?
  - Who else will examine them?
- Getting the right questions at the right time
- Commissioning/monitoring research
- Getting timely and useful results to decision-makers
  - To allow them to act on the answers
- The programme is:
  - Needs- led (relevance to the NHS)
  - Science- added (seeks to add value at every stage)

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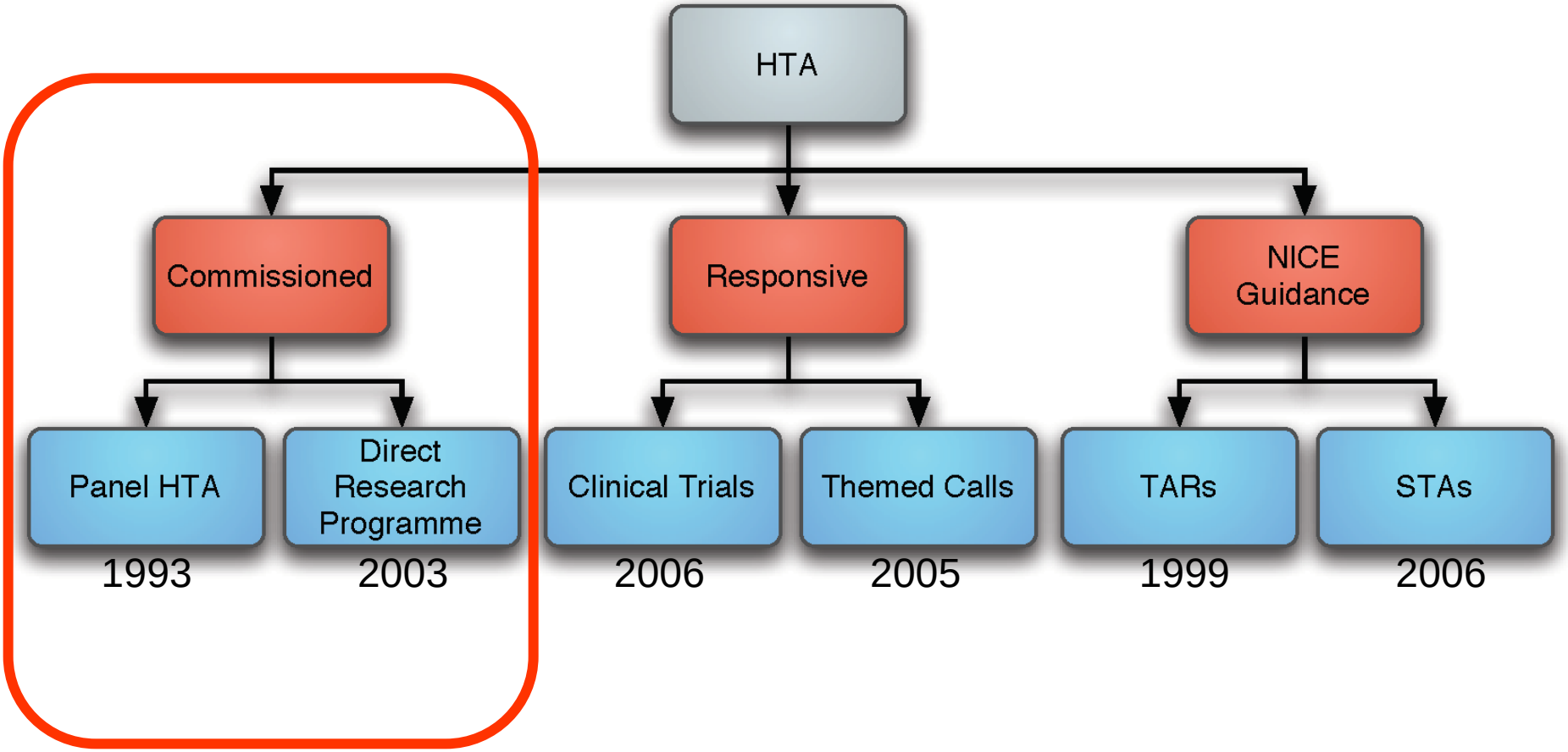

Commissioned research – us pulling the community to do "dull but needed" research

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HTA – commissioned workstream

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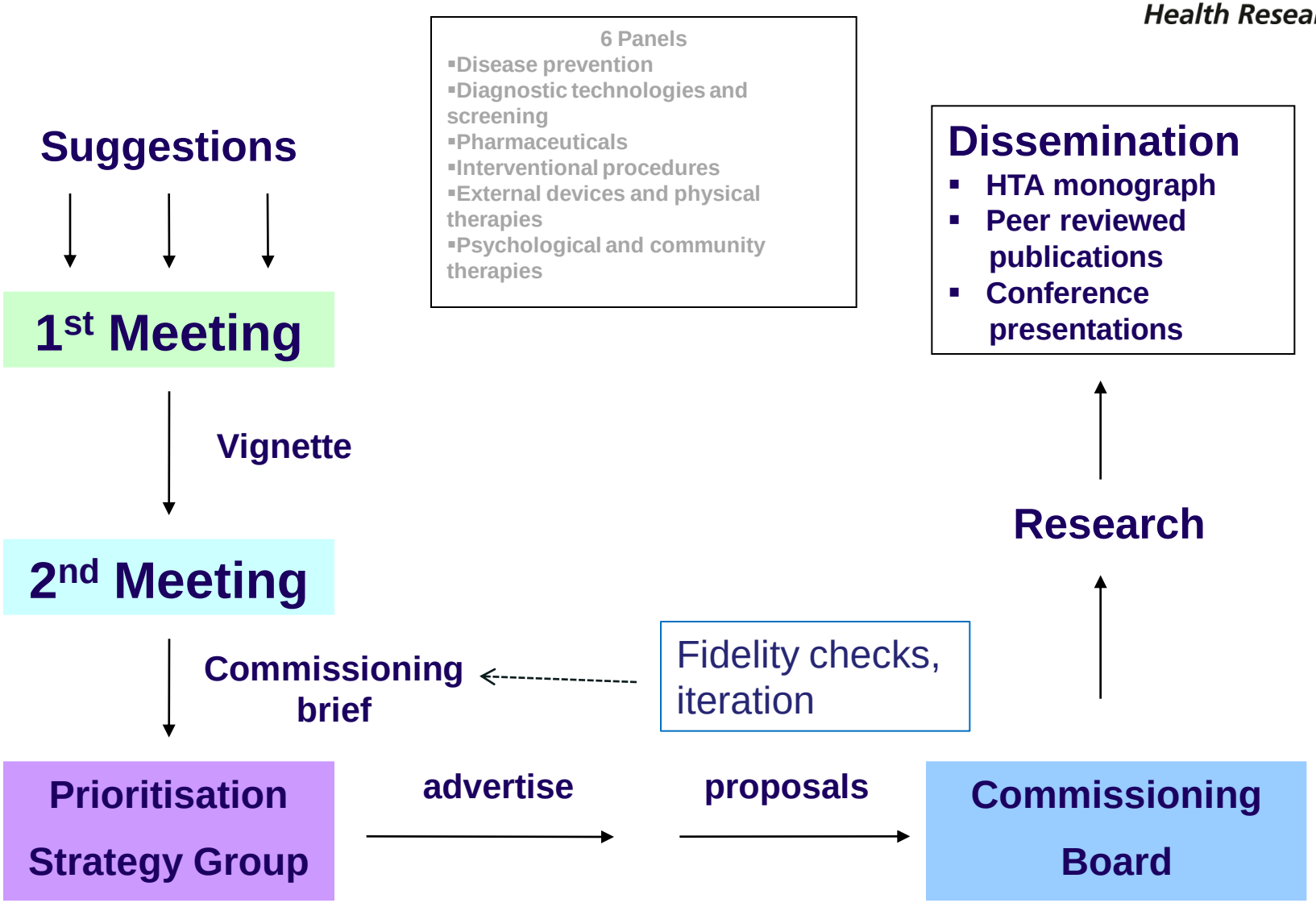

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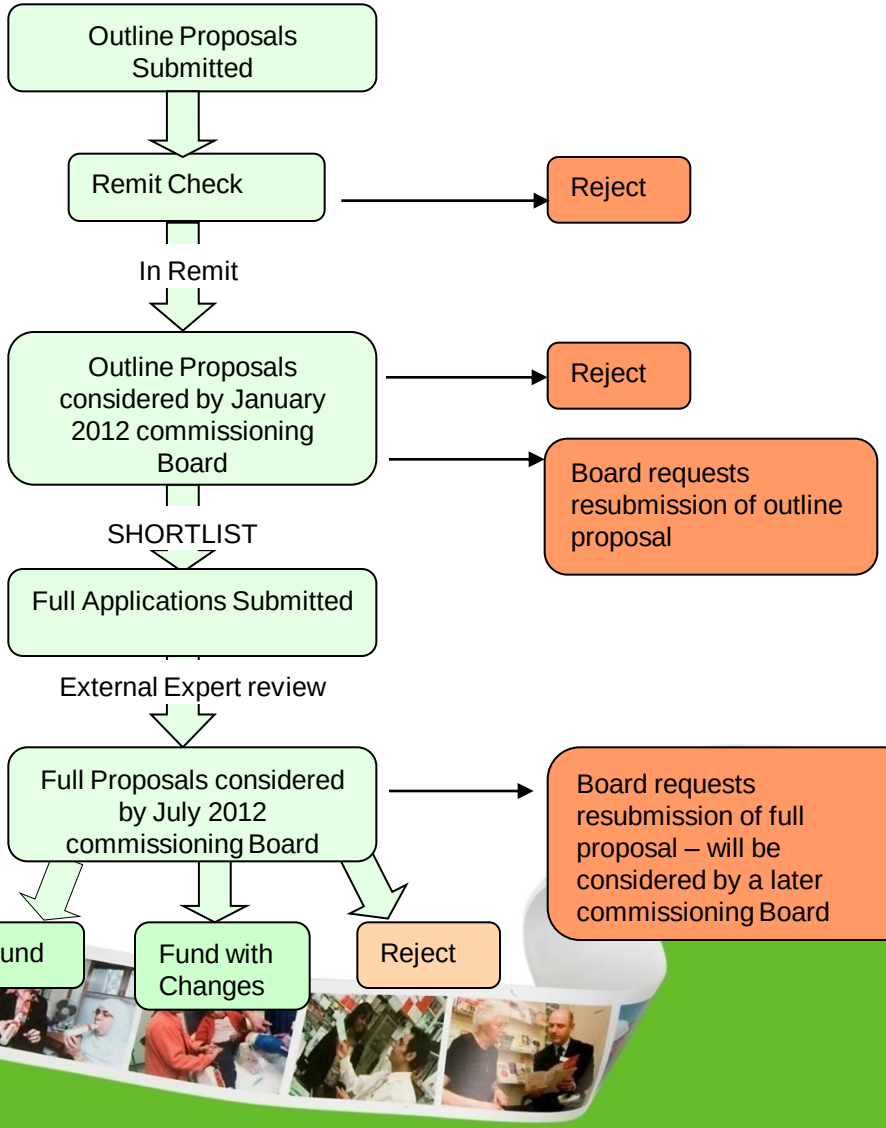

Process for the Board discussion

- A lead Designated Board Member (DBM) introduces the proposal
- 2nd and 3rd DBMs add further comments
- Discussion then opens to the rest of the Board
- For outline proposals, decision is made to shortlist or reject
- For full applications, Board scores the proposal
- The Chair summarises decision and key points for feedback

Commissioned Primary Research examples

- **Published in Lancet**
  - EVAR
  - SANAD
  - NACHBID
  - FOOD
  - PAC-MAN
  - ECMO
  - CAST
  - CBT in back pain
- **Published in NEJM**
  - C3PO
  - BELL'S trial

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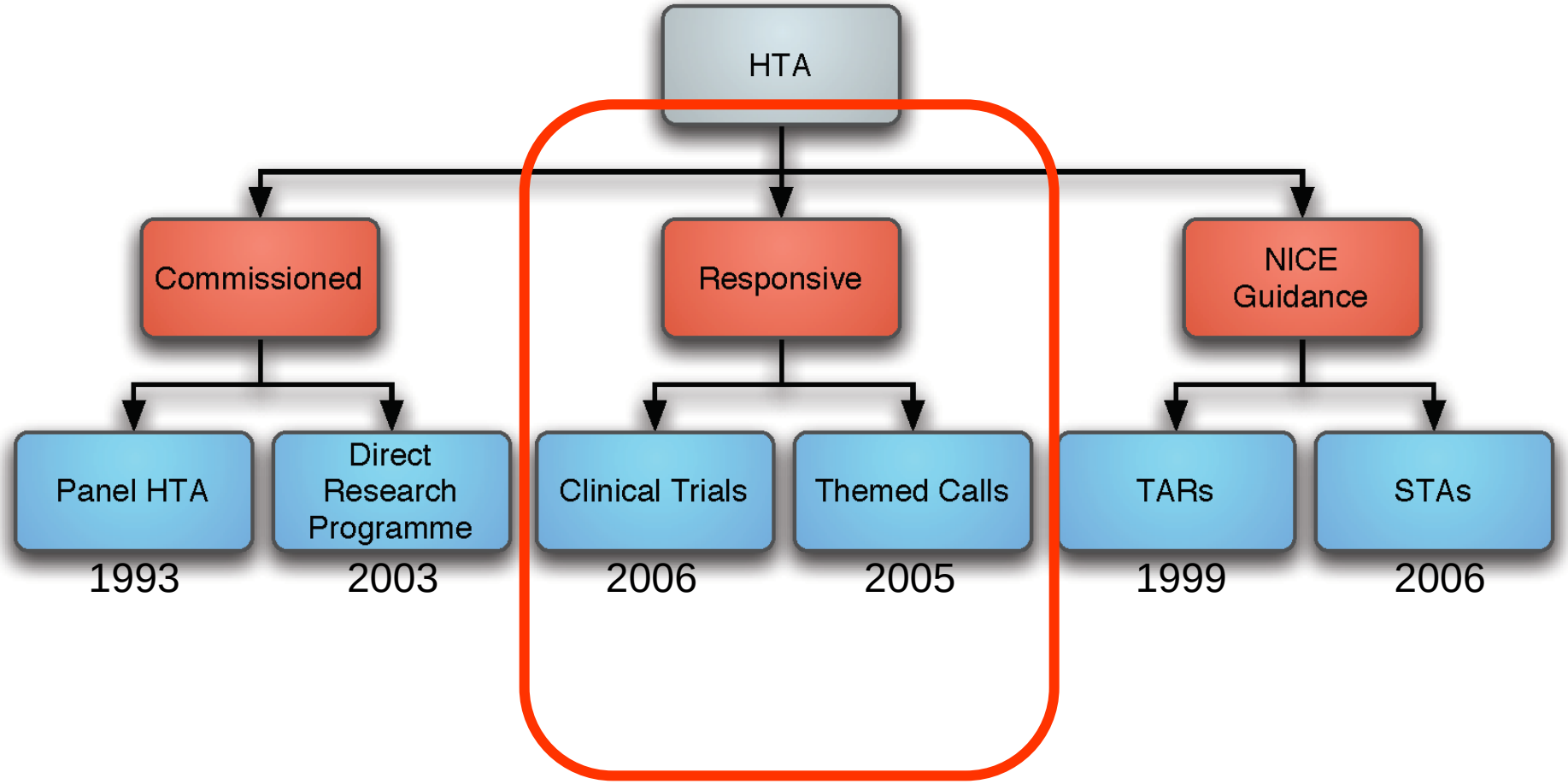

Responsive mode – research community pulling us

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HTA – responsive workstream - but still needs led

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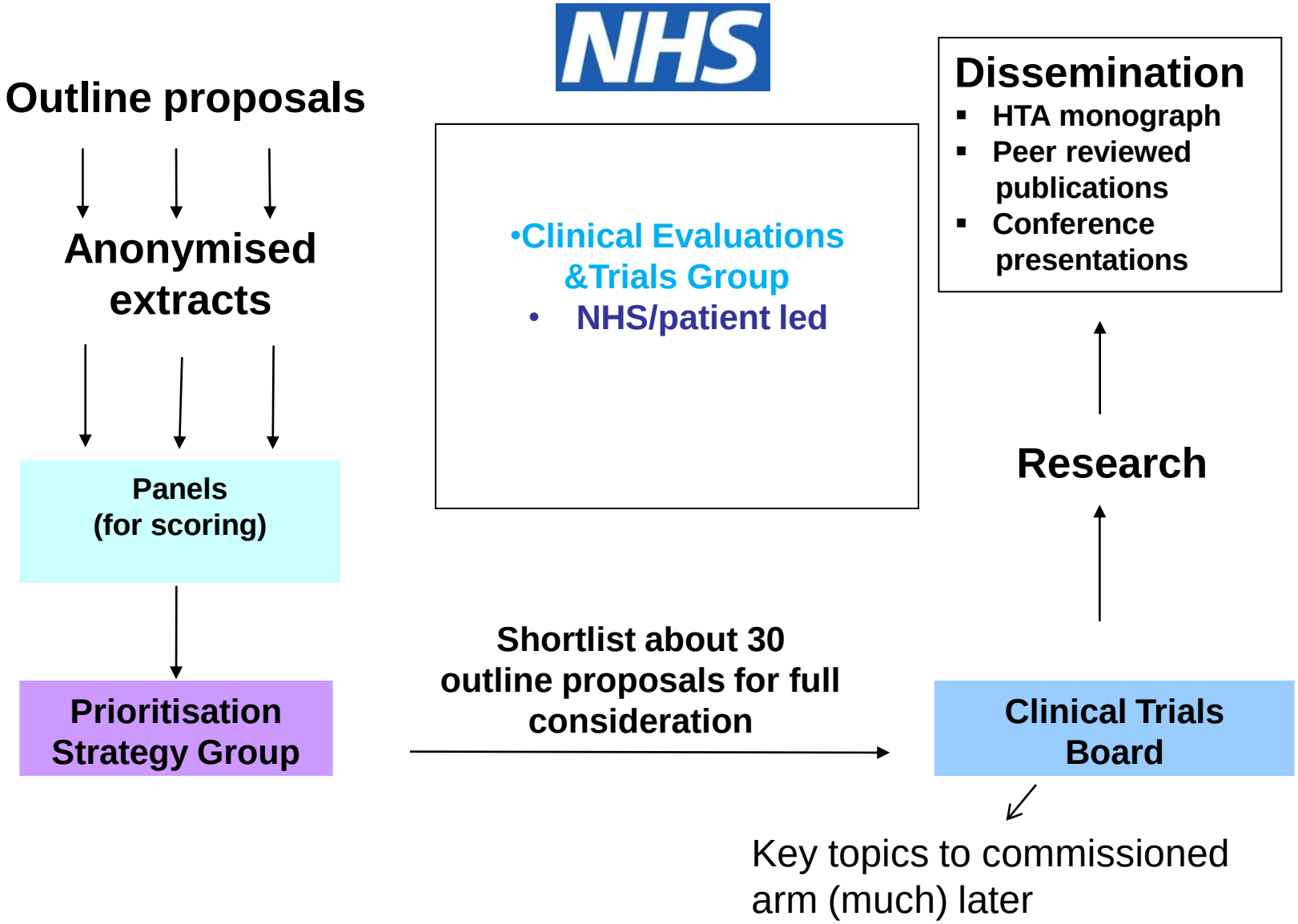

Examples of responsive mode

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- Themed calls
  - M4C, trauma & emergency care, healthcare acquired infections,
  - diagnostics
  - Mental health, stroke

- IVAN – bevicizumab v ranibizumab
  - **I**nhibit **V**EGF in **A**ge-related choroidal **N**eovascularisation.

CRASH-2 Clinical Randomisation of an Antifibrinolytic in Significant Haemorrhage

- Persephone - comparing six months Trastuzumab treatment with twelve months, in women with early stage breast cancer

HTA – reaches the parts that other funders do not reach

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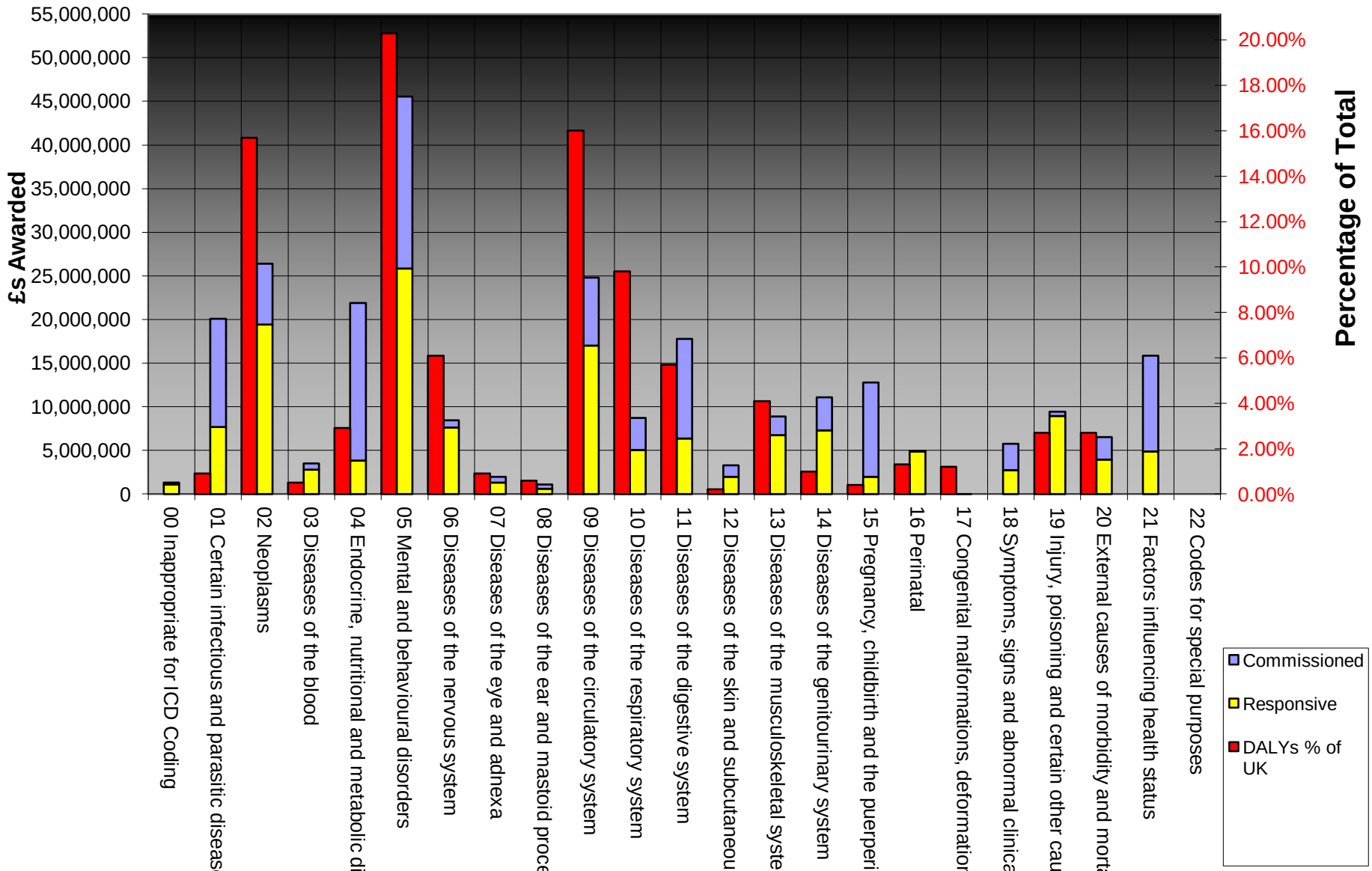
HTA Awards relative to ICD10 mapped DALYs over 5 years (Jan 2007 - Dec 2011)
showing value and percentage of overall
£s Awarded
55,000,000
50,000,000
45,000,000
40,000,000
35,000,000
30,000,000
25,000,000
20,000,000
15,000,000
10,000,000
5,000,000
0
Percentage of Total
20.00%
18.00%
16.00%
14.00%
12.00%
10.00%
8.00%
6.00%
4.00%
2.00%
0.00%
00 Inappropriate for ICD Coding
01 Certain infectious and parasitic diseases
02 Neoplasms
03 Diseases of the blood
04 Endocrine, nutritional and metabolic diseases
05 Mental and behavioural disorders
06 Diseases of the nervous system
07 Diseases of the eye and adnexa
08 Diseases of the ear and mastoid process
09 Diseases of the circulatory system
10 Diseases of the respiratory system
11 Diseases of the digestive system
12 Diseases of the skin and subcutaneous tissue
13 Diseases of the musculoskeletal system
14 Diseases of the genitourinary system
15 Pregnancy, childbirth and the puerperium
16 Perinatal
17 Congenital malformations, deformations
18 Symptoms, signs and abnormal clinical
19 Injury, poisoning and certain other causes
20 External causes of morbidity and mortality
21 Factors influencing health status
22 Codes for special purposes
ICD 10 Chapters
Commissioned
Responsive
DALYs % of UK

HTA dermatology related trials

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- Antibiotics for acne - Topical benzoyl peroxide and benzoyl peroxide/erythromycin combinations are similar in efficacy to oral oxytetracycline and minocycline and are not affected by propionibacterial antibiotic resistance

- Softened water for eczema study (SWET)

- The Bullous Pemphigoid Steroids and Tetracyclines Study (BLISTER)

BLISTER Study

Ozolins M et al Comparison of five antimicrobial regimens for treatment of mild to moderate inflammatory facial acne vulgaris in the community: randomized controlled trial. Lancet. 2004 Dec 18-31;364(9452):2188-95.

NETS as a system

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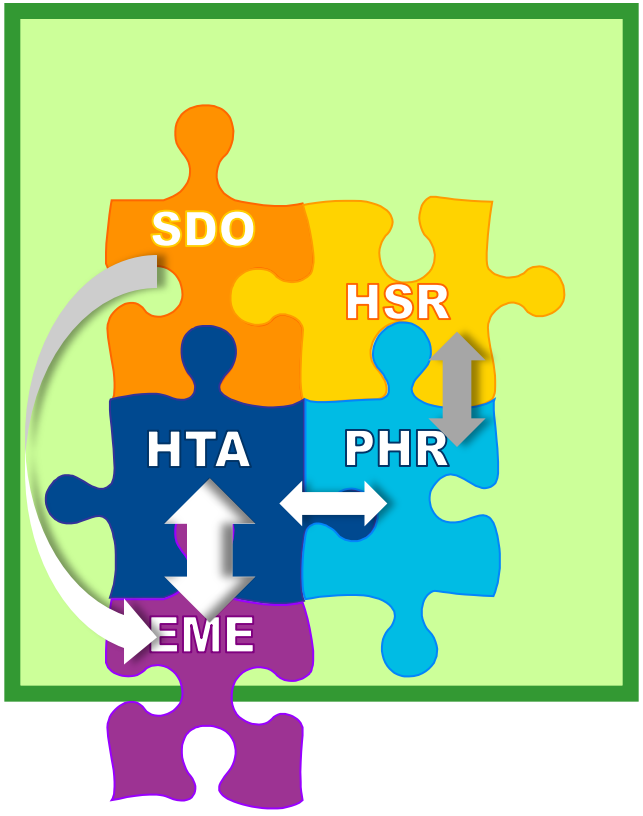
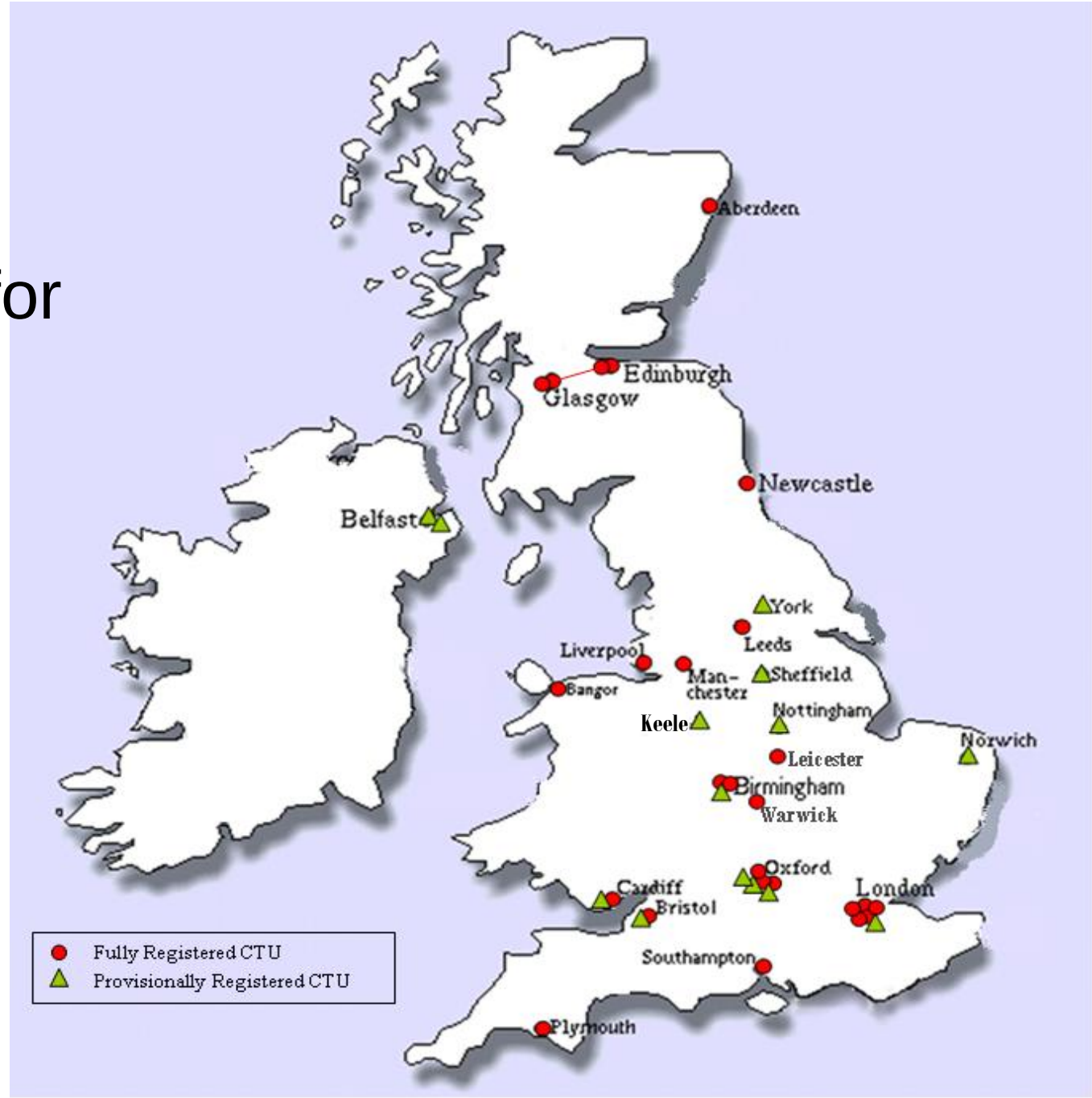
Facilitating researchers, speeding review
Transfers between NETS programmes
Active collaboration between programmes
Directors' meetings
Joint calls
Meeting with networks



Support for Clinical Trials Units

25 (in England) now supported by HTA programme



Nottingham Clinical Trials Unit - Windows Internet Explorer

http://ctu.nottingham.ac.uk/ctu/default.asp

File Edit View Favorites Tools Help

Google nottingham clinical trials unit Search nottingham clinical trials unit More

Nottingham Clinical Trials Unit

Page Tools

Nottingham CTU

Login

Home | Background | Randomisation | Supported Trials | Resources | Partners | Contacts | Vacancies | Useful Links

Welcome to the University of Nottingham Clinical Trials Unit

The Nottingham Clinical Trials Unit (NCTU) is a UK Clinical Research Collaboration registered clinical trials unit, based at the University of Nottingham. It is an academic clinical trials unit with expertise in the design and conduct of trials. NCTU aims to collaborate with clinicians and other trialists in the conduct of high quality randomised trials that address important health questions.

From January 2012, those wishing to collaborate with NCTU should complete our proposal outline. The completed outline should be submitted to ctu@nottingham.ac.uk. Submitted outlines will be considered against the NCTU criteria for engagement by our Proposal Review Committee.

NCTU also provides a web-based randomisation service. For those wishing to apply to use the randomisation service only (i.e. not wishing to collaborate) the Randomisation Request Form should be completed and sent to ctu@nottingham.ac.uk.

Nottingham CTU annual report for 2010

LATEST NEWS

11-Jan-2012
Seminar: "HTA Commissioning".

24-Mar-2011
Seminar: "Improving quality of Trials (MRC Network of Hubs)".

16-Feb-2011
SWET trial results available.

10-Dec-2010
Job: Clinical Trial Manager x2.

news in full

UKCRC Registered Clinical Trials Units

We have moved and our telephone numbers have changed.

mailto:ctu@nottingham.ac.uk?subject=Randomisation%20Request

Local intranet 100%

start 4 Micros... 2 Micros... HTA 2009 Program v... 2 Intern... Search Desktop 08:57

How many clinical trials?

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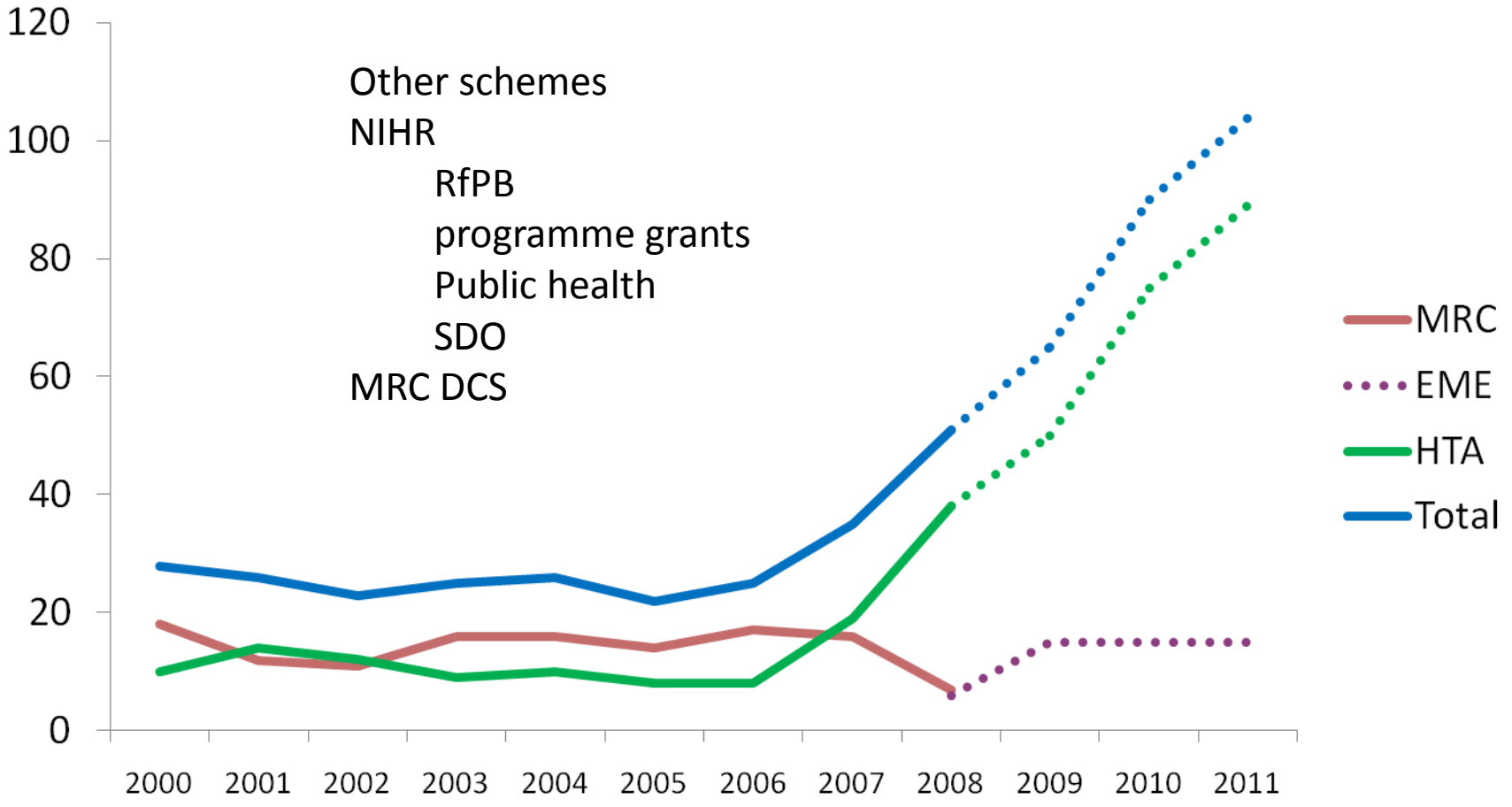

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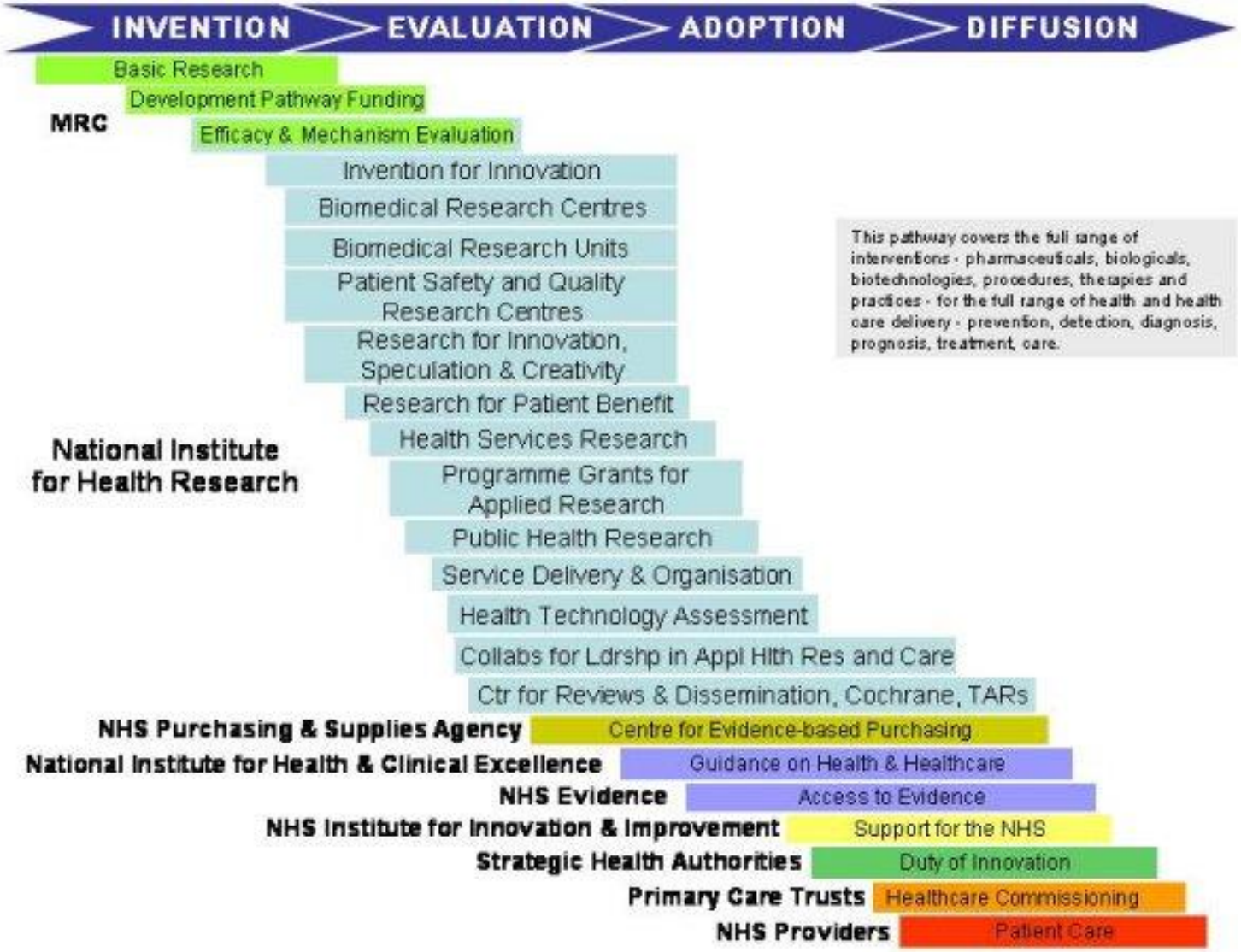

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Successful proposals

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- Good question – grounded in reality of clinical practice
- Winning team – breadth and depth
- Well written and coherent proposal

Successful proposals.....

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- Preparatory work
- Involve a Clinical Trials Unit
- Realistic costing
- Keep it simple

Why full applications can fail:

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- Over-ambitious recruitment
- Sample size too small
- Lack of clear writing and inconsistencies
- Key people missing from the team
- Drifting off commissioning brief

Why full applications can fail (2)

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- Not being open about problems
- Lack of clinical equipoise
- Lack of depth in understanding the clinical problem
- Not responding to Board feedback
- Not good value

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Getting the balance right between pushing and pulling research

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HTA

Key messages

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1. The clinical research landscape in the UK *has been* transformed (and very rapidly)

2. Other countries like US are following rapidly

3. Needs-led, science added research

4. Never been a better time or place to do applied health research