

R&D – realising the vision

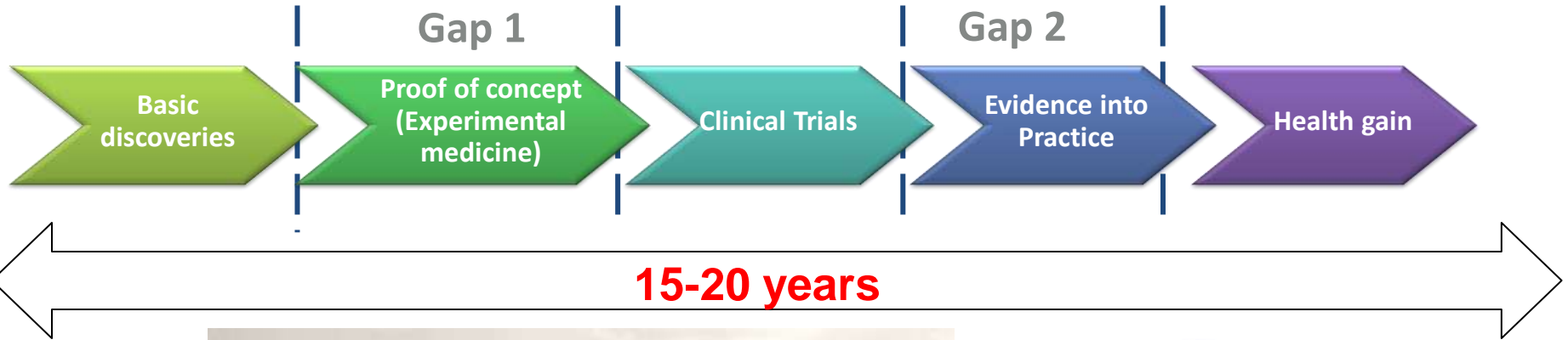
Professor Stephen Smye, Theme Director, NIHR CRN &
R&I Director, Leeds Teaching Hospitals NHS Trust



R&D

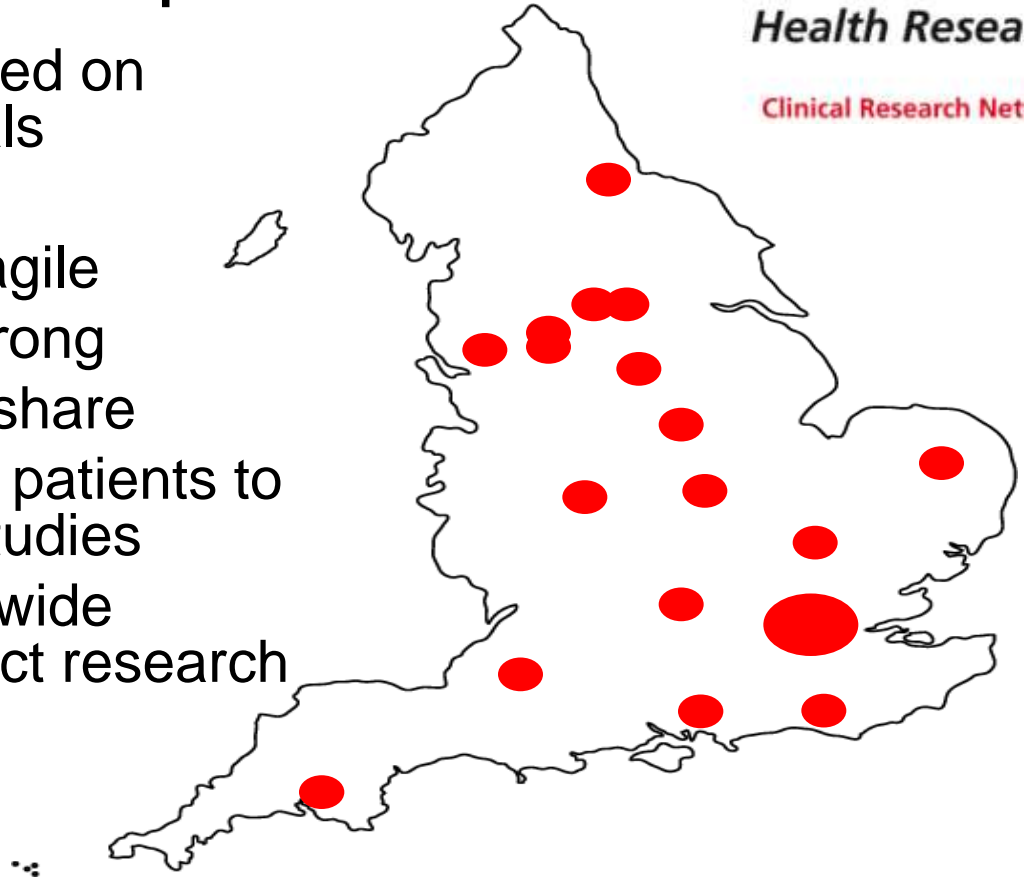


The challenge of translation



The challenge of participation

- Research mainly centred on acute teaching hospitals
- Culyer funding
- Academic medicine fragile
- “Discovery” science strong
- Loss of global market share
- Limited opportunity for patients to participate in clinical studies
- Funders lacked nationwide infrastructure to conduct research

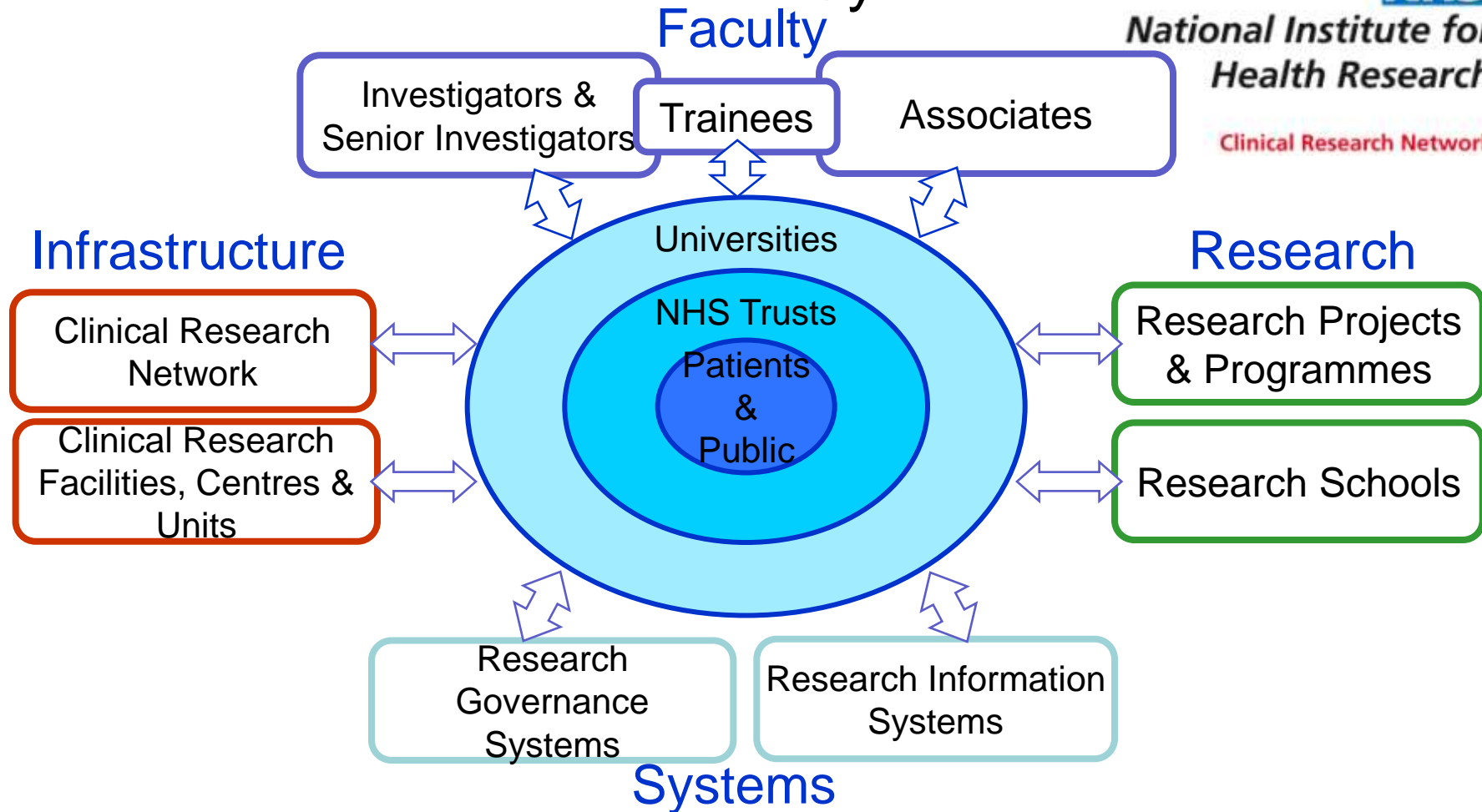


The NIHR Health Research System



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NHS

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Taking stock of achievements...

99%+ of Trusts engaged in Portfolio studies: including hard-to-reach Trusts
We recruited more than 630,000 patients in 2012/13
The number of studies achieving NHS Permission within 40 days has improved five-fold in 2 years

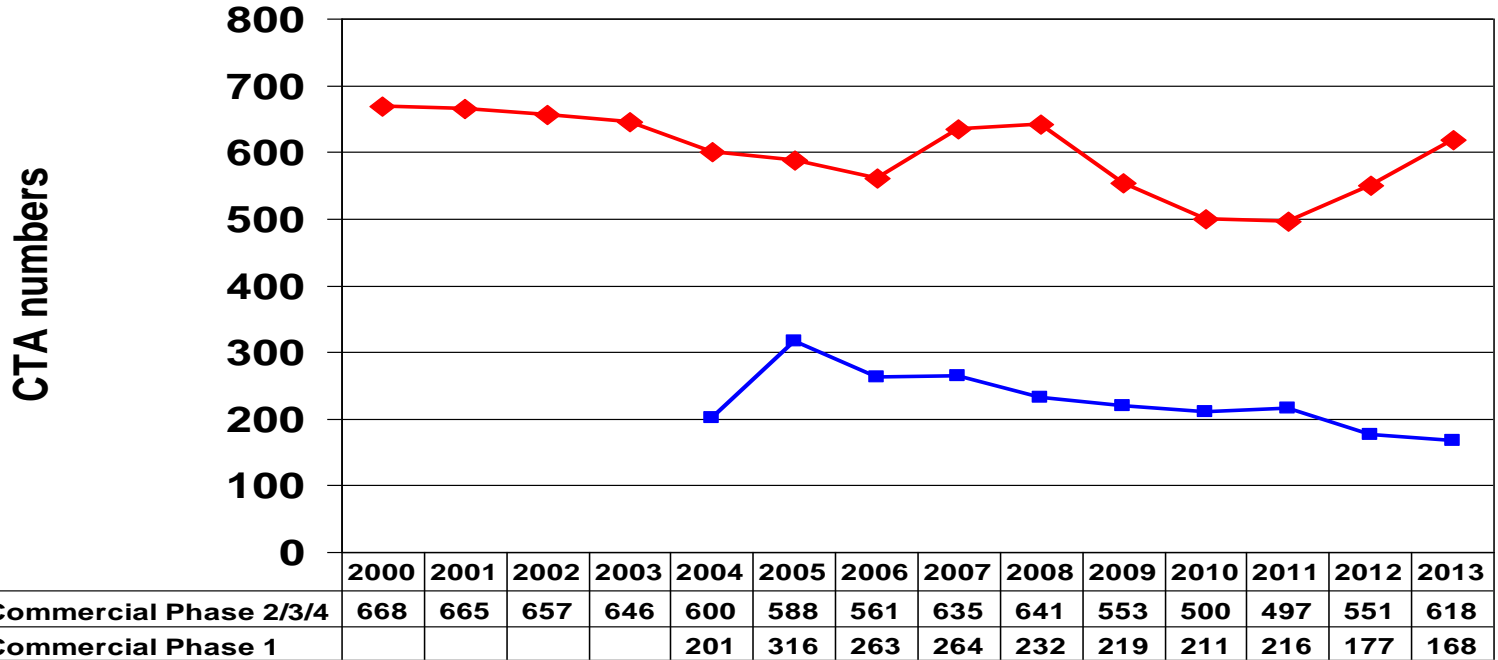


The number of commercial contract studies rose to 685 in 2012/13 – our highest ever

The number of commercial contract studies delivering to time and target doubled

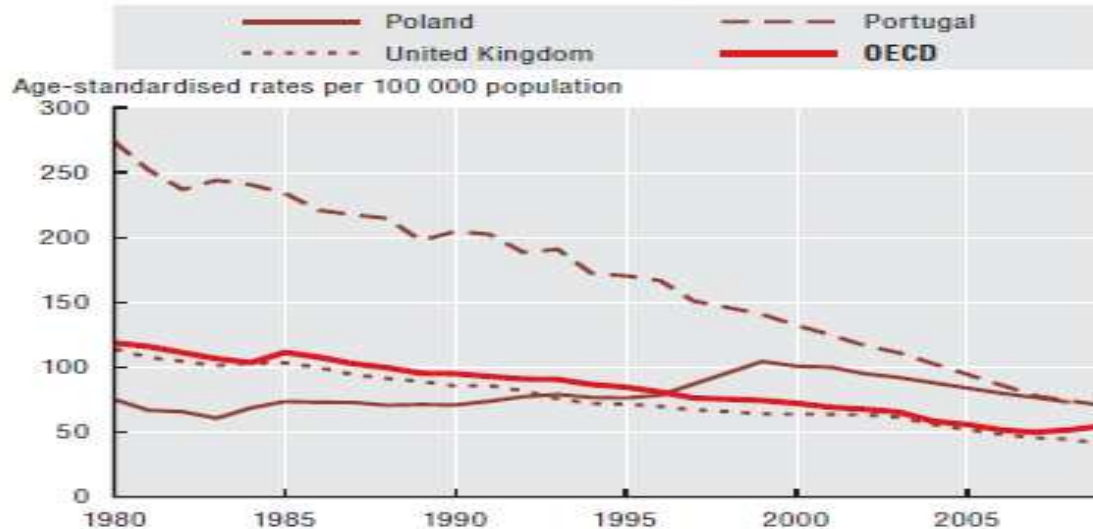
Global recognition

UK Commercial applications received



Improving outcomes

1.3.4 Trends in stroke mortality rates, selected OECD countries, 1980-2009



Source: OECD Health Data 2011.

StatLink <http://dx.doi.org/10.1787/888932523405>

OECD (2011),
*Health at a Glance
2011: OECD
Indicators*, OECD
Publishing.
http://dx.doi.org/10.1787/health_glance-2011-en

R&D



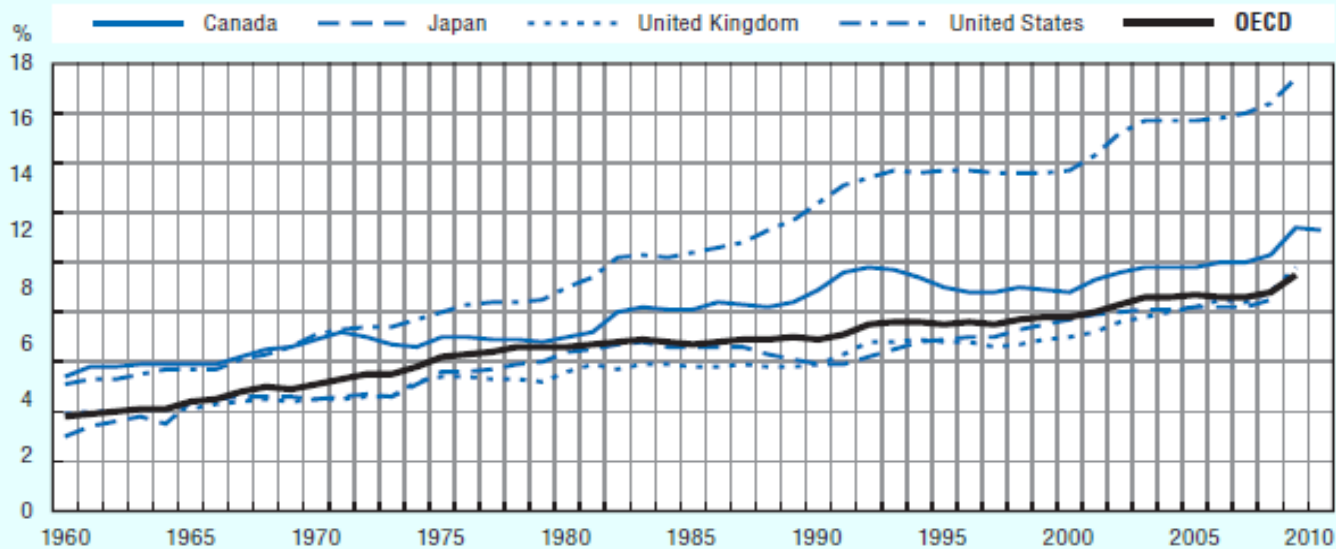
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Health challenges

Health expenditure as a share of GDP, 1960-2009, selected OECD countries



Source: OECD Health Data 2011.

StatLink <http://dx.doi.org/10.1787/888932523215>

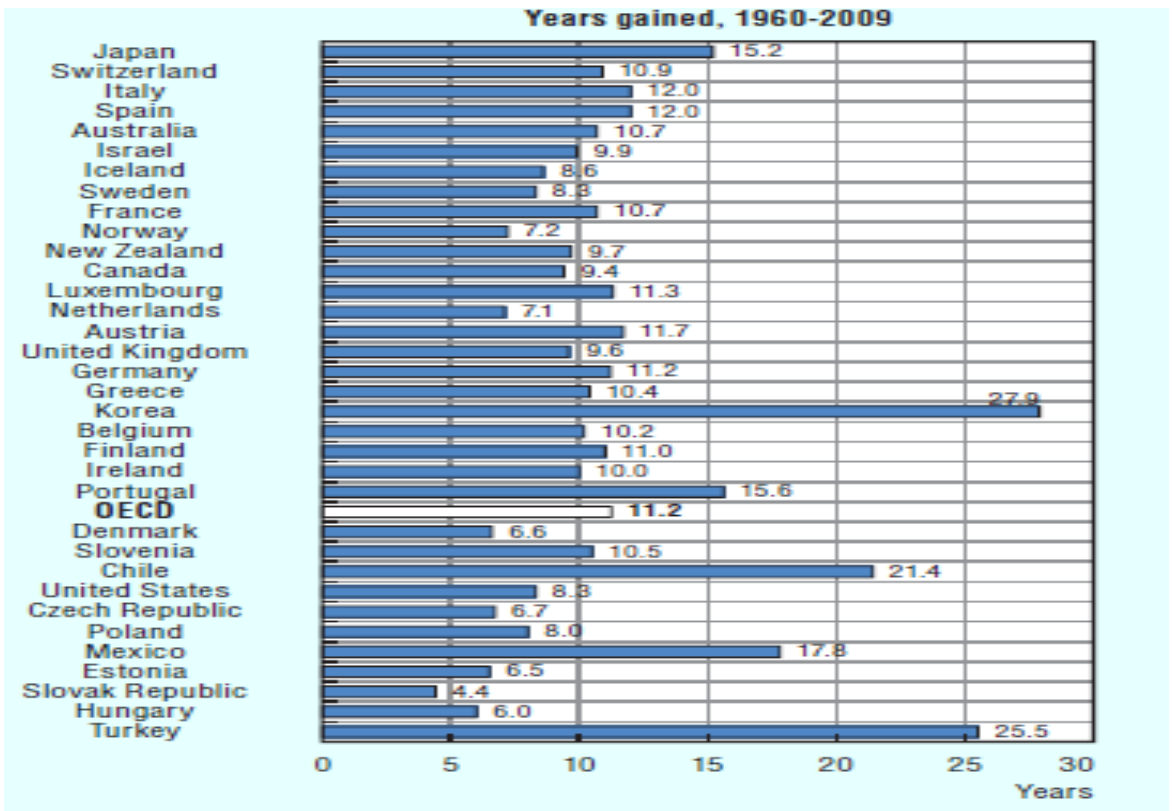
OECD (2011),
*Health at a
Glance 2011:*
OECD Indicators,
OECD
Publishing.
http://dx.doi.org/10.1787/health_glance-2011-en

Life expectancy – years gained since 1960 (2009)



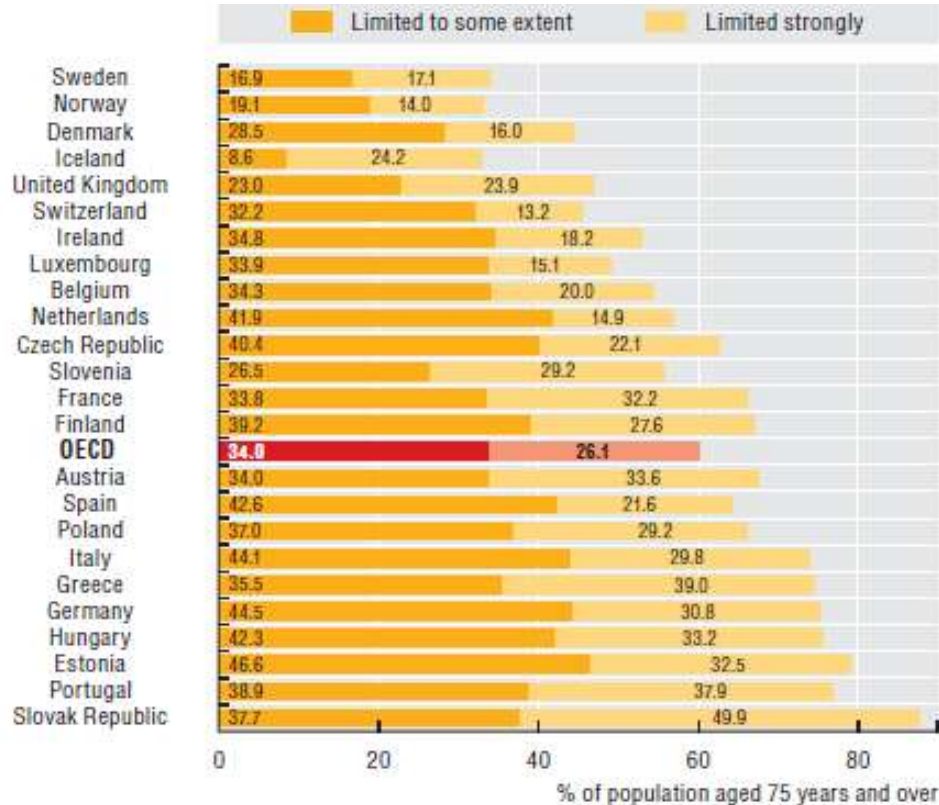
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OECD (2011), *Health at a Glance 2011: OECD Indicators*, OECD Publishing.
http://dx.doi.org/10.1787/health_glance-2011-en

Limitations in daily activities, population aged 75 and over, 2009



OECD (2011), *Health at a Glance 2011: OECD Indicators*, OECD Publishing.
http://dx.doi.org/10.1787/health_glance-2011-en



[NIHR home](#)

[Focus on .. home](#)

[About Dementia](#)

[Get involved](#)

[NIHR in action](#)

Search



Focus on Dementia

Message from the CMO



This site provides a snapshot of the work of the National Institute for Health Research is doing in the area of dementia. Dame Sally Davies, Chief Medical Officer, introduces this new resource. [Read more >>](#)

About dementia research



Alistair Burns, National Clinical Director for Dementia gives us an overview of dementia research today. [Read more >>](#)

Living with dementia



Ken Clasper (left) is living with dementia and actively involved in dementia research. Ken and his wife and carer Janice explain how dementia affects their daily life and how research has helped them to cope. [Read more >>](#)

About dementia



Dementia is a common condition that affects about 800,000 people in the UK. It is estimated that by 2021, this number will have increased to around 1 million. [Read more >>](#)

NIHR in action



[Hear from some of our researchers](#)



[Dementia research case studies](#)



[Find out what studies we fund](#)

Getting involved



We encourage members of the public to become actively involved in clinical research, forming a partnership with researchers to improve the relevance and design of studies. [Read more >>](#)

Research and Growth: Strategy for UK Life Sciences



“Life science - and the UK’s role in it - is at a crossroads.

Behind us lies a great history of discovery, from the unravelling of DNA to MRI scanning and genetic sequencing.

We can be proud of our past, but this government is acutely aware that we cannot be complacent about the future.” *David*

Cameron, December 2011

R&D

*It is not in the stars to hold our destiny
but in ourselves*



Shaping the future.....

- Science
- Industry
- Patients
- NHS



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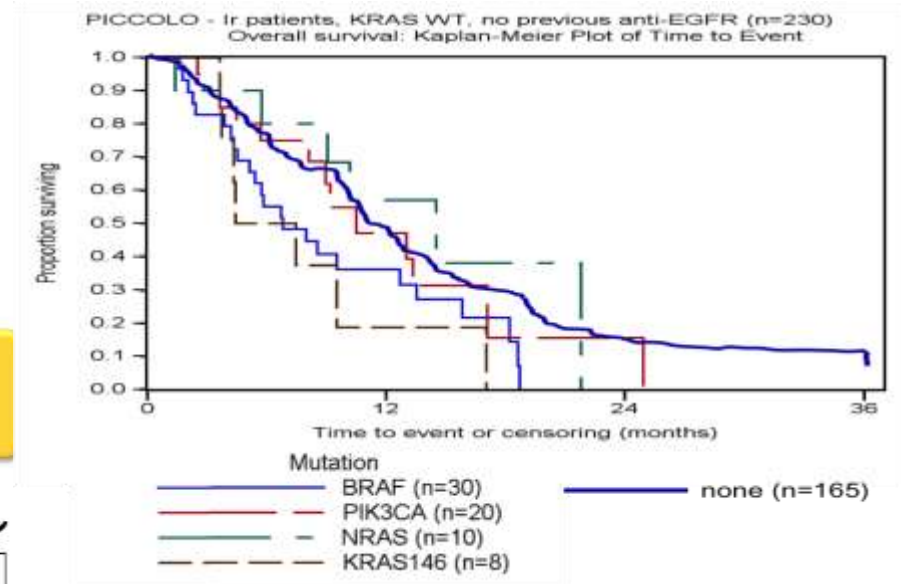
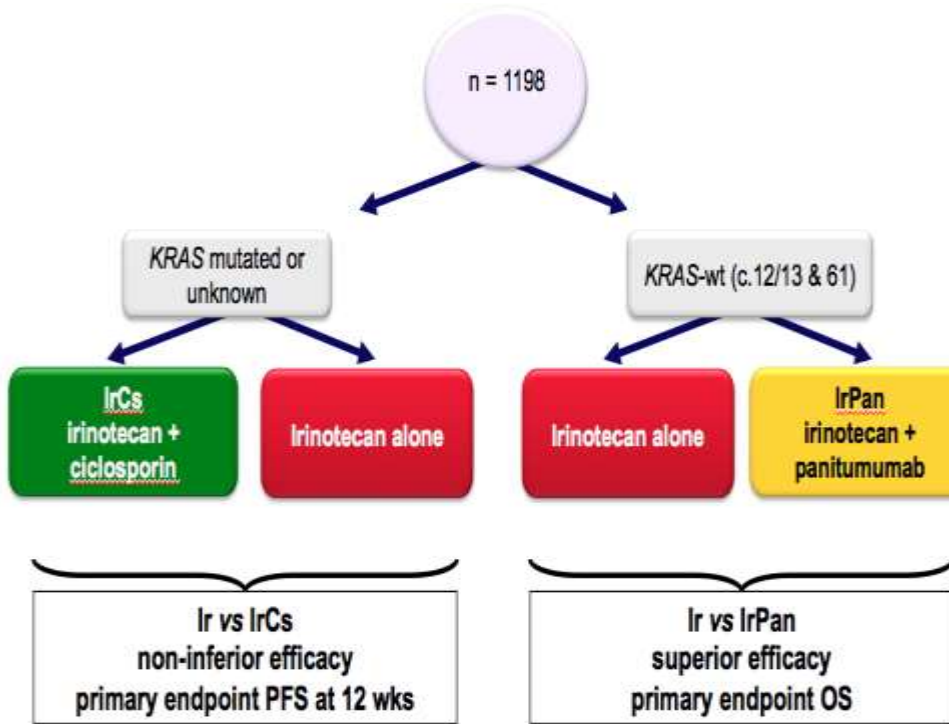
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Genomics
england



- 100,000 whole genomes by 2017

Advanced disease – Piccolo multiple mutation testing



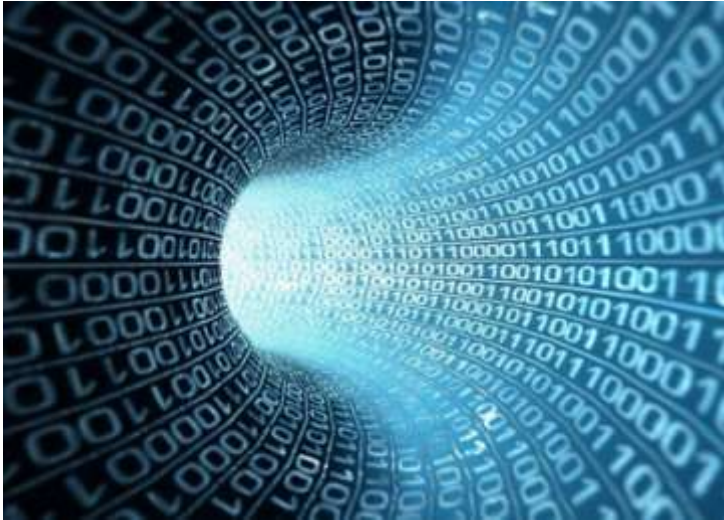
Seymour MT et al *The Lancet Oncology*,
Volume 14, Issue 8, July 2013, Pages
749-759

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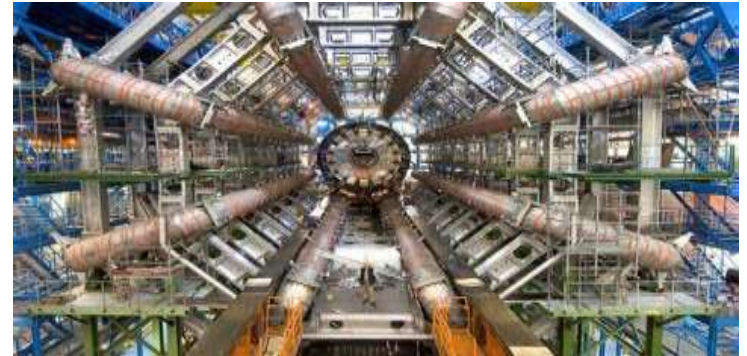


“When you can measure what you are speaking about, and express it in numbers, you know something about it, when you cannot express it in numbers, your knowledge is of a meagre and unsatisfactory kind; it may be the beginning of knowledge, but you have scarcely, in your thoughts, advanced to the stage of science.”

William Thomson, 1st Baron Kelvin

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<http://www.crick.ac.uk/>



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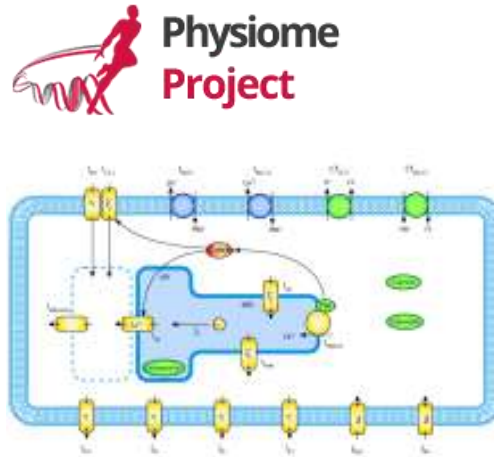
AN ATLAS OF EXPRESSION

The first draft of the complete human proteome has been made in a decade in the making. In the process, the effort has also delivered lessons about technology and biology.



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<http://physiomeproject.org/>



<http://www.cambridgecancer.org.uk/>

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UK Life Sciences Industry



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- 4,500 firms, 165,000 staff, R&D spend £5bn - 8% of UK total manufacturing.
- > 300 pharmaceutical companies, 78,000 people, turnover £31bn pa.
- Medical technology and medical biotechnology sectors employ 87,000 people, turnover £18.4bn pa.
- third biggest “industry” in the UK



Real World Study



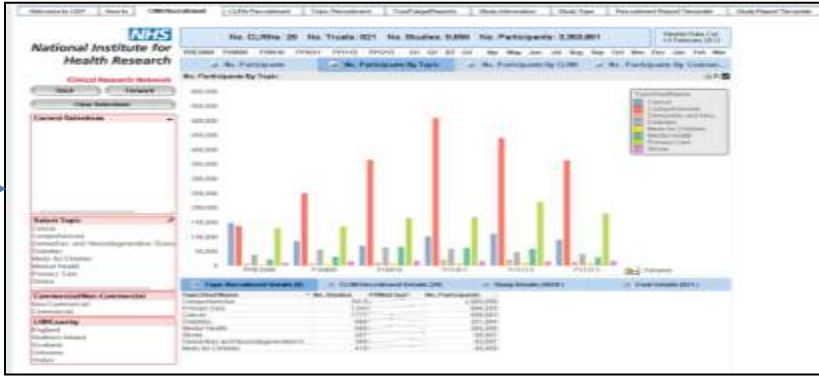
Data collected outside the controlled constraints of conventional clinical trials to evaluate what is happening in normal clinical practice.





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BIG data



CPRD
MORE DIMENSIONS TO DATA



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Salford Lung Study



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- First major pre-licence pragmatic real-world effectiveness study
- GSK selected NHS - total population coverage, e records in primary care and GP prescribing, full hospital EPR & integrated e-records with primary care)
- COPD and asthma studies – both on-track (COPD c2000 patients out of target of 2800
- 70 separate pharmacies engaged in the project & > 60 GP practices
- Study expanded outside Salford to help speed recruitment which includes getting data from a different CCG area and a different hospital site - technology is capable of scaling across the NHS
- > 150 jobs created
- unique electronic near-real-time safety monitoring system and e systems also record all health-related events linked to the study outcomes - the number of study visits is kept to a minimum (2)



For more information on the Salford Lung Study, please visit the study website at www.salfordlungstudy.co.uk

Prof M Gibson

Shaping the future.....

- Science *Novel Disease Indications for AstraZeneca Clinical Compounds*

AWARD: \$15,000 USD | DEADLINE: 5/31/14 | ACTIVE

- Industry

SOLVERS: 638 | POSTED: 3/24/14

AstraZeneca is seeking novel clinical indications for a select set of compounds previously in clinical development. These “patient-ready” compounds, with evidence of human target coverage and manageable tolerability, are available for novel clinical indications- preferably in diseases with significant unmet medical need.

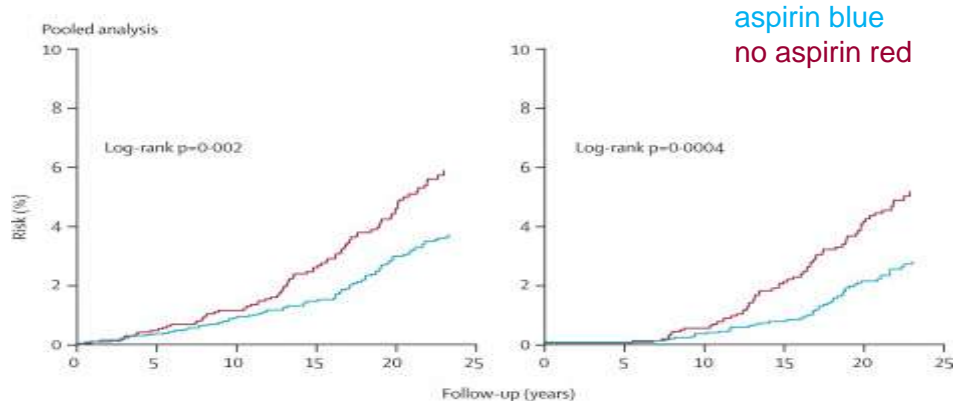
- Patients

- NHS

Source: InnoCentive

Aspirin

- Observational and RCT evidence that aspirin
 - prevents colorectal adenoma and CRC
 - alters natural history of established CRC (inhibition of metastasis)
- Uncertainty about
 - Mechanism(s)
 - Optimum dose ('low' 75 mg vs 'high' 300 mg) for chemoprevention *versus* adverse events (GI bleeding and haemorrhagic stroke)
 - Appropriate target population (age, family history)



10-14 yrs after randomisation HR
0.26 (0.12-0.56) if aspirin \geq 5 yrs

Lancet 2007;**369**:1603



The seAFood (**S**ystematic **E**valuation of **A**spirin and **F**ish **O**il) polyp prevention trial

Double-blind randomised placebo-controlled trial

2 x 2 factorial design;

EPA free fatty acid (FFA) enteric-coated 2 g daily

aspirin EC 300 mg daily

CI Professor Mark Hull *Trials* 2013;**14**:237

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'... it is quite hard to find out about research - there aren't the notices in surgeries and very few in hospitals. It is only if the clinician or GP is directly involved or has been asked to find volunteers that the information is given..' - Patient

Public appetite, patient demand

- 82 per cent of people believe it is important for the NHS to offer opportunities to take part in healthcare research.
- Less than 7% said they would never take part in a clinical research study.
NIHR Clinical Research Networks Survey May 2012
- 69% of women with ovarian cancer say they would travel to another hospital to be on a trial
Target Ovarian Cancer, Pathfinder Study Report 2013
- Over 70% of patients look for information about clinical trials
ecancer 5 235 2011 'Information needs of cancer patients'

What we do already



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International
Clinical Trials Day
20th May

This marks the day in which
James Lind began his study
on scurvy.

**Mystery
shopper**



UK Clinical Trials Gateway
www.ukctg.nihr.ac.uk



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THE NHS
CONSTITUTION
the NHS belongs to us all

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Shaping the future.....

- **Science** **Objective**
To assess the impact of electronic health record (EHR) implementation on primary care diabetes care.
- **Industry** **Principal Findings**
patients exposed to the EHR were significantly more likely to receive “optimal care” when compared with unexposed patients ($p < .001$), with an estimated difference of 9.20 percent (95% CI: 6.08, 12.33) in the final year between exposed patients and patients never exposed.
- **Patients** **Conclusion**
Implementation of a commercially available EHR in primary care practice may improve diabetes care and clinical outcomes.
Herrin, J., da Graca, B., Nicewander, D., Fullerton, C., Aponte, P., Stanek, G., Cowling, T., Collinsworth, A., Fleming, N. S. and Ballard, D. J. (2012), The Effectiveness of Implementing an Electronic Health Record on Diabetes Care and Outcomes. Health Services Research, 47: 1522–1540.
- **NHS**

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“ We linked the ACCF National Cardiovascular Data registry & the STS Adult Cardiac Surgery database to claims data from the Centers for Medicare and Medicaid Services for the year 2004-2008...”

Analysis of linked data

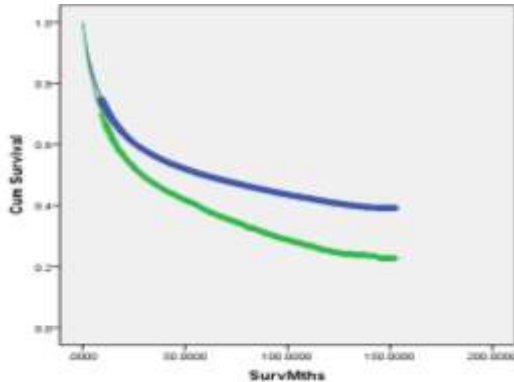


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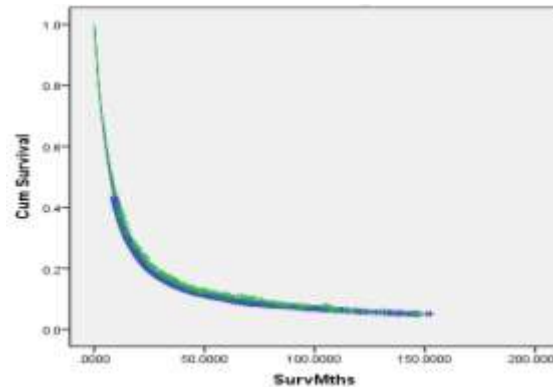
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- University of Leeds and Leeds Teaching Hospitals with N&Y Cancer Registry and Information Service and NHS IC - Cancer registration and HES data
- Impact of co-morbidity at diagnosis on
 - Overall survival and recurrence-free survival

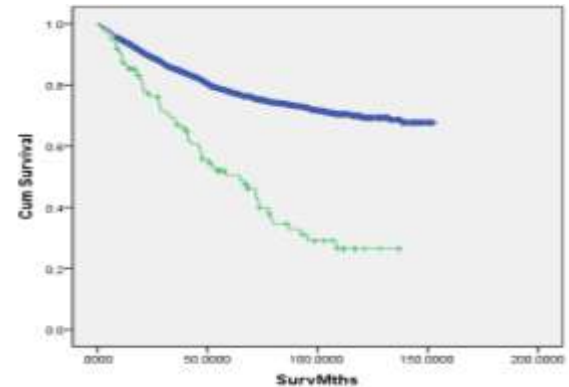
All



Cancer A



Cancer B



Courtesy of G Hall, University of Leeds

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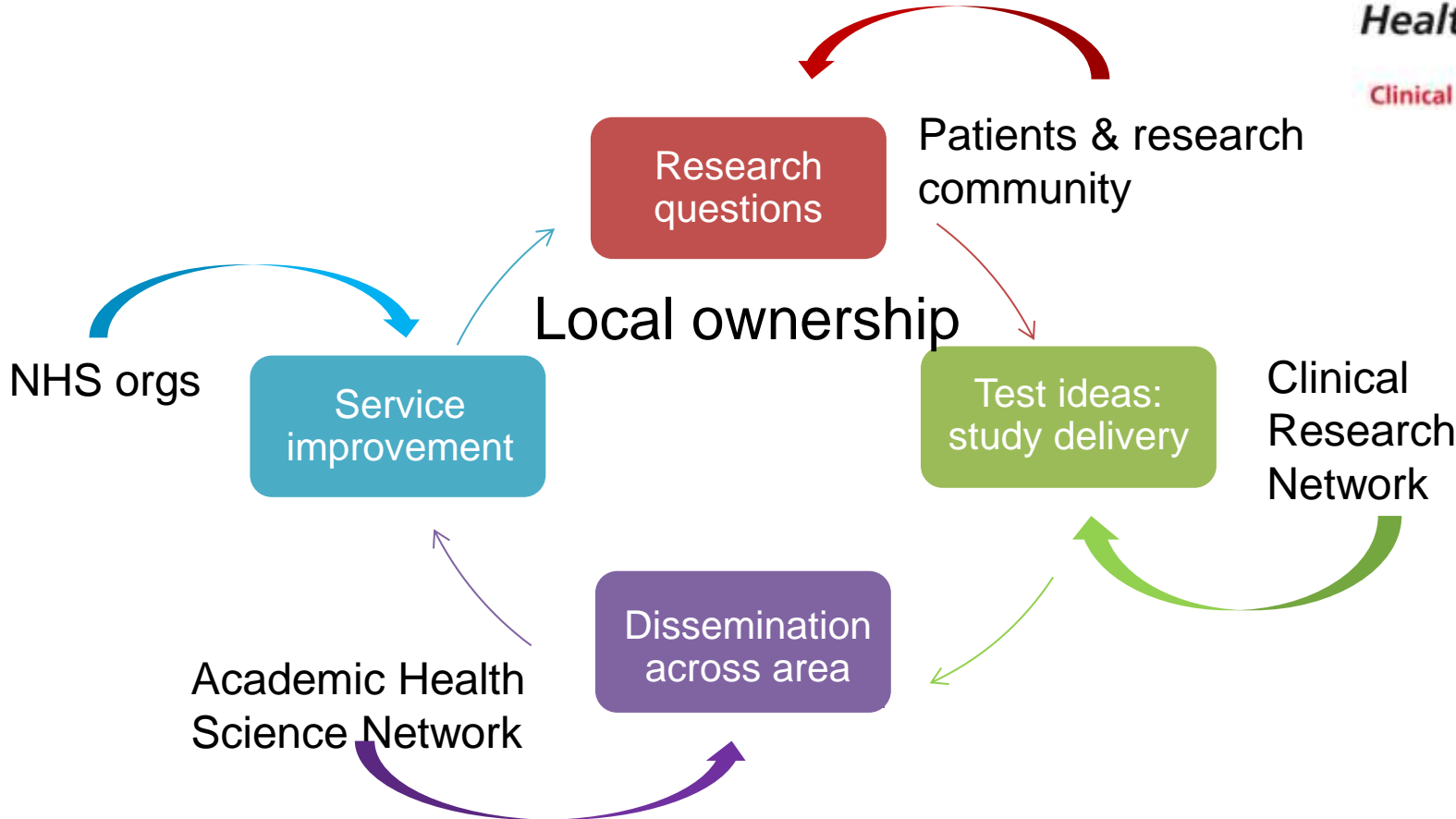


Innovation & research



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R&D management



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R&D management

- service
- patient-facing
- known for leading-edge use of data in the NHS

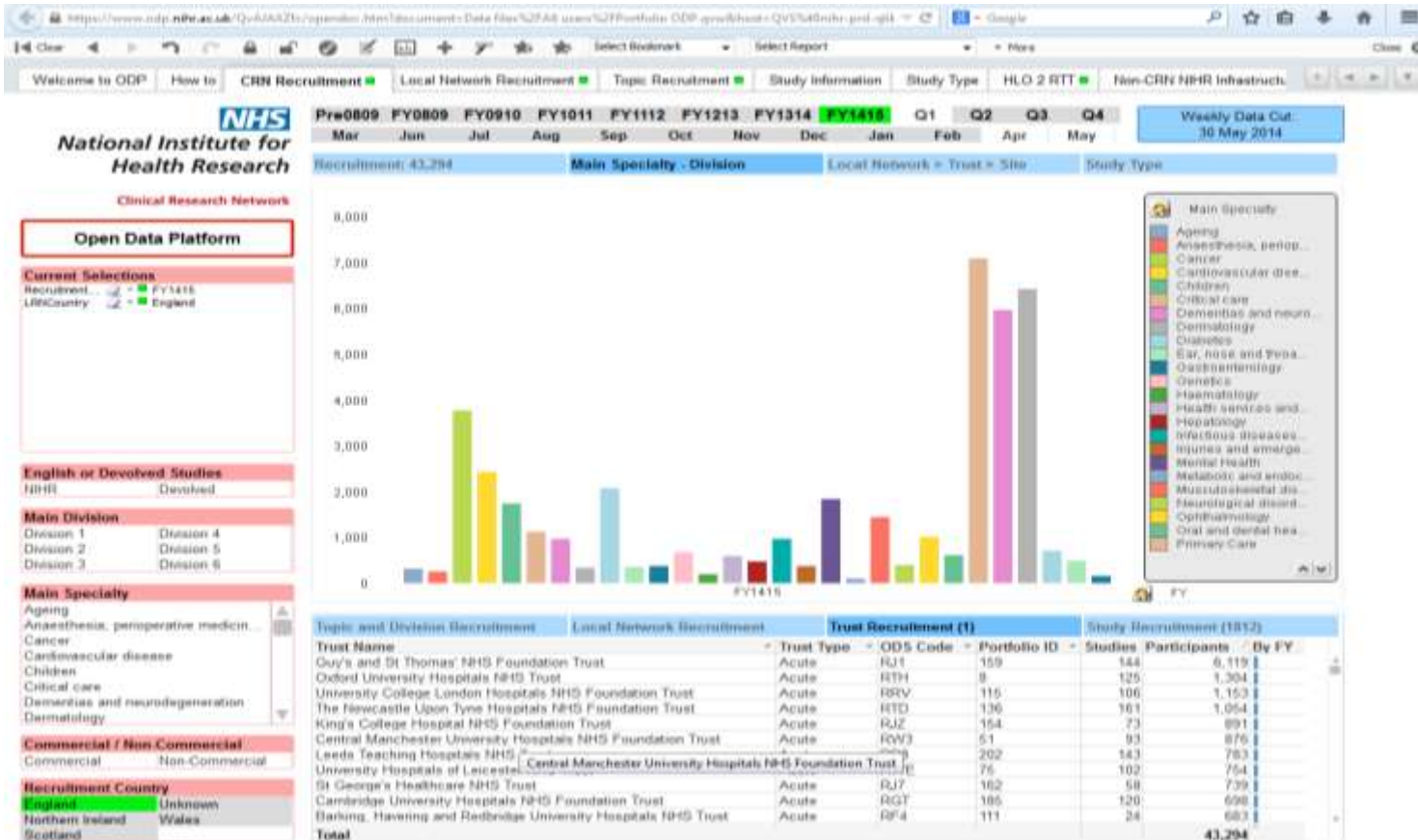


R&D management – data informed



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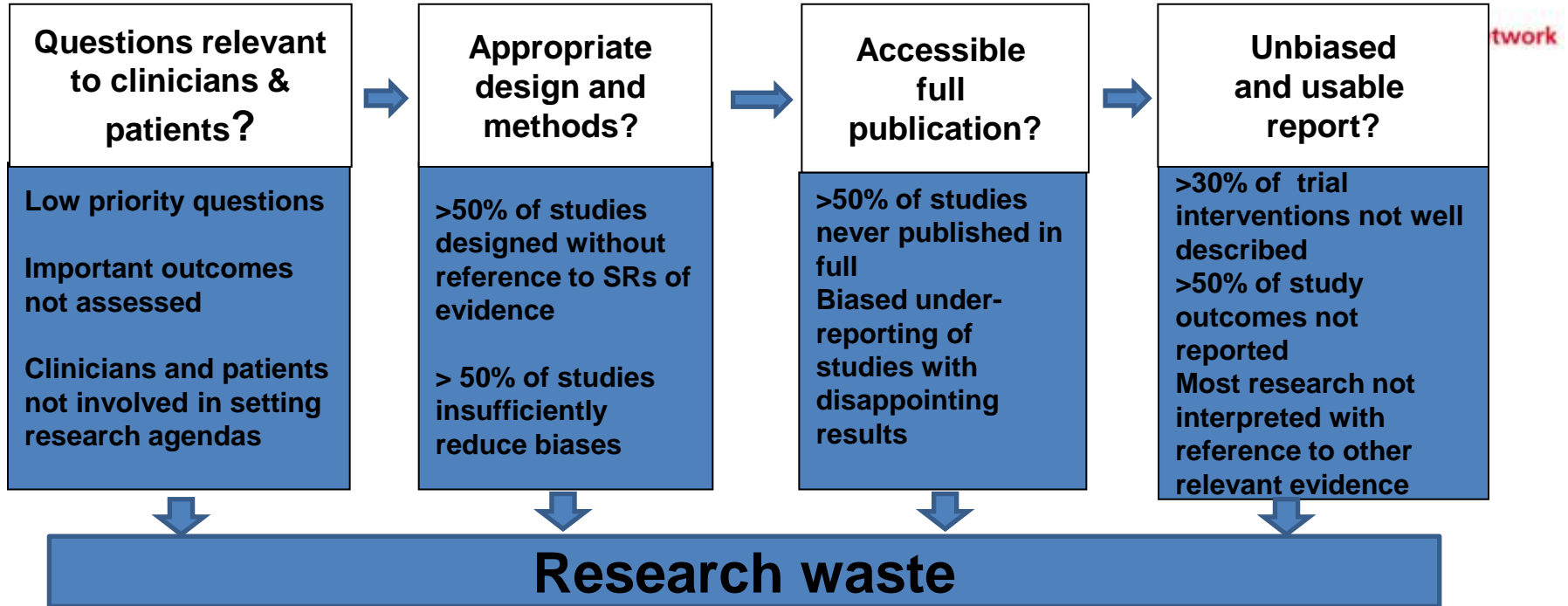


R&D management

- use of information to integrate services
- access and support to use information
 - Including access to people's own health and care records
- Empower service users
- Improve efficiency of research



R&D management – efficient research



Avoidable waste in the production and reporting of research evidence, *Iain Chalmers, Paul Glasziou Lancet 2009; 374: 86–89*

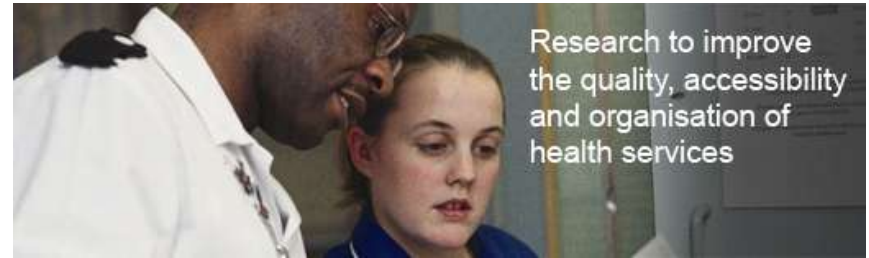
R&D management

- secondments to industry, academia & clinic
- element in general manager training
- managers **and** researchers



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**Health Services and Delivery
Research (HS&DR) Programme**

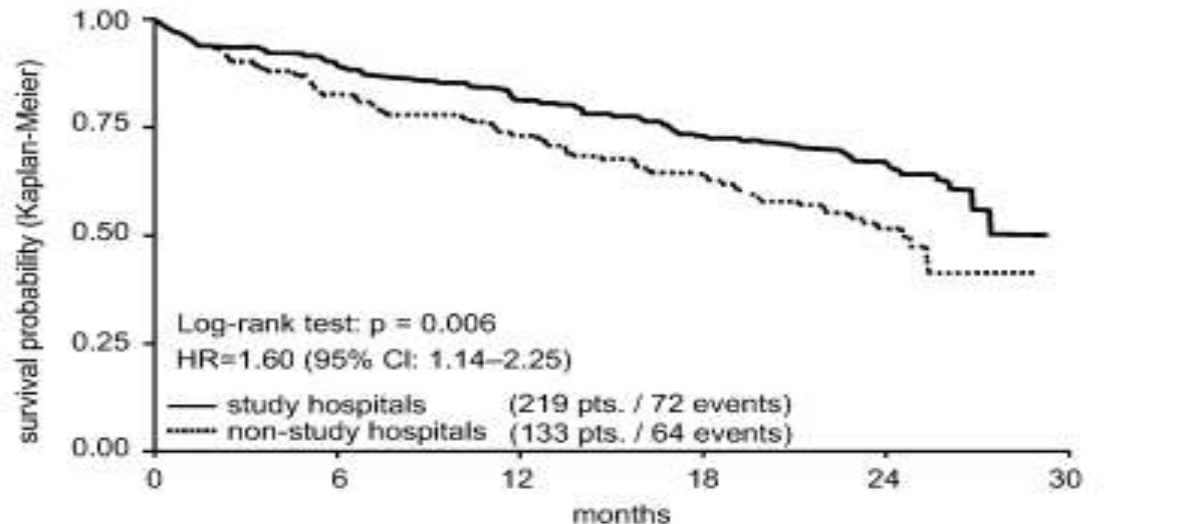
<http://www.nets.nihr.ac.uk/programmes/hsdr>

R&D management



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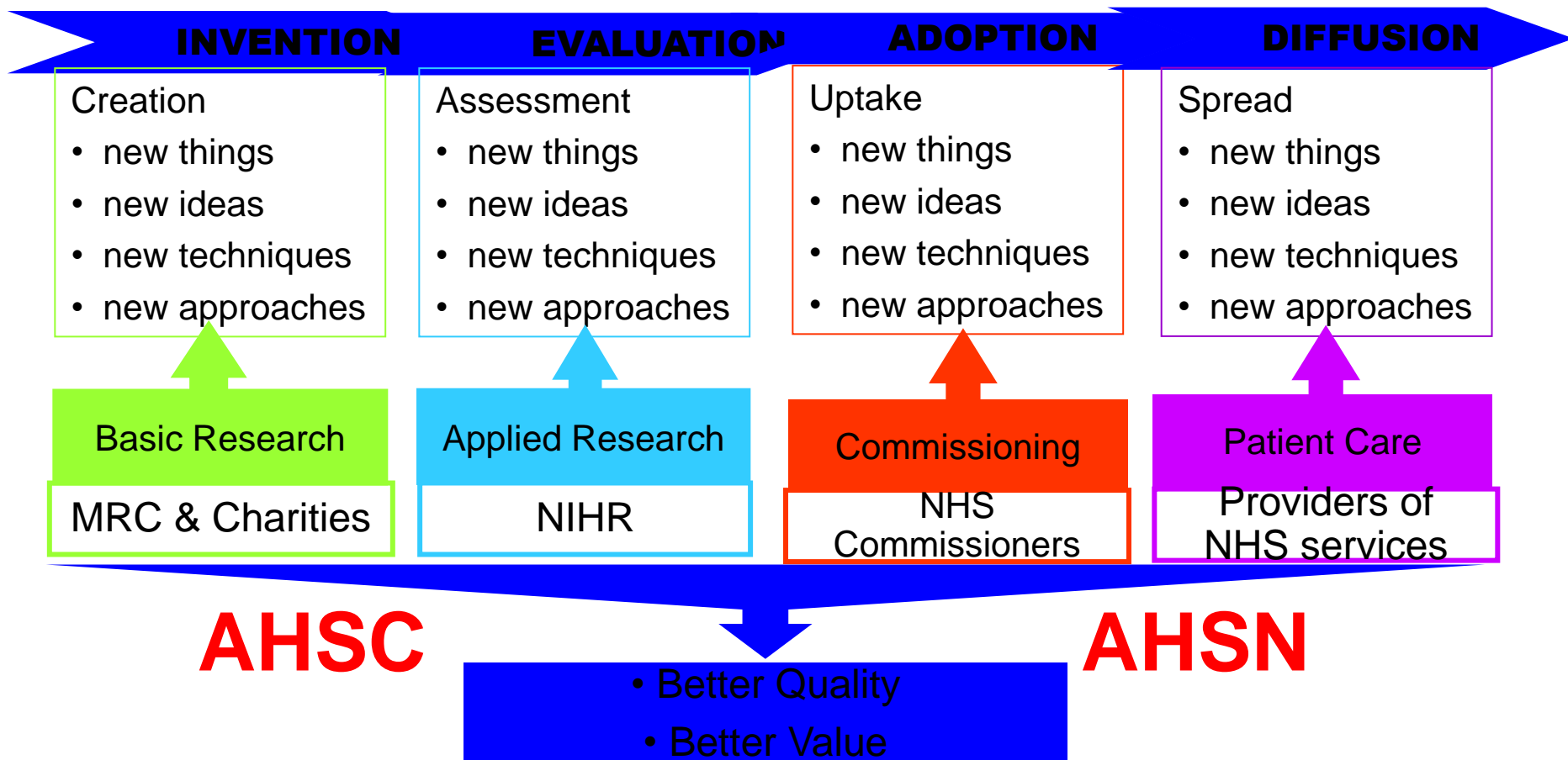


Pts. at risk	219	184	161	141	73	study hospitals
	133	107	92	80	36	non-study hospitals

Pattern of care and impact of participation in clinical studies on the outcome in ovarian cancer

Du Bois et al, *Int J Gynecol Cancer* 2005, 15, 183.

R&D management – system pilots



R&D management – a community of practice

- networked and networking



*“Building research active communities
Our Stroke Research Network has shown how long-term focus on involvement and engagement can lead to better participation, having grown the research participation rate in the stroke population from 1% to nearly 10%.
The Mental Health Research network has similarly shown how patients and researchers working together can lead to more effective recruitment strategies meaning that studies are four times more likely to recruit to time and to target.”*

Research

- for all
- informed by data
- focused on patient outcomes
- delivering economic benefit
- managed



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Research – the way we provide best care