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

15-20 years
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

Faculty
- Investigators & Senior Investigators
- Trainees
- Associates

Infrastructures
- Clinical Research Network
- Clinical Research Facilities, Centres & Units

Research
- Research Projects & Programmes
- Research Schools

Systems
- Research Governance Systems
- Research Information Systems

Universities
NHS Trusts
Patients & Public

Investigators & Senior Investigators
Trainees
Associates

National Institute for Health Research
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

Global recognition

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
UK Commercial applications received

<table>
<thead>
<tr>
<th>Year</th>
<th>Commercial Phase 2/3/4</th>
<th>Commercial Phase 1</th>
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<tbody>
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<td>2000</td>
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<td>2012</td>
<td>551</td>
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<tr>
<td>2013</td>
<td>618</td>
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</table>
Improving outcomes

R&D
Health challenges

Life expectancy – years gained since 1960 (2009)

http://dx.doi.org/10.1787/health_glance-2011-en
Limitations in daily activities, population aged 75 and over, 2009

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 >>
“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
Shaping the future.....

- Science
- Industry
- Patients
- NHS
Shaping the future…..

- Science
- Industry
- Patients
- NHS

- 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
Shaping the future.....

“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
Shaping the future.....

- Science
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- NHS
Shaping the future…..

• Science

• Industry

• Patients

• NHS

http://www.crick.ac.uk/
Shaping the future.....

- Science
- Industry
- Patients
- NHS

http://physiomeproject.org/
Shaping the future.....

- Science
- Industry
- Patients
- NHS
UK Life Sciences Industry

• 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.
BIG data

National Institute for Health Research
Clinical Research Network

CPRD
MORE DIMENSIONS TO DATA
Shaping the future…..
Salford Lung Study

- 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)

Prof M Gibson
Shaping the future…..

- **Science**
  
  **Novel Disease Indications for AstraZeneca Clinical Compounds**
  
  AWARD: $15,000 USD | DEADLINE: 5/31/14 | ACTIVE SOLVERS: 638 | POSTED: 3/24/14

- **Industry**
  
  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 ≥ 5 yrs

*Lancet* 2007;369:1603
The seAFOod (Systematic Evaluation of Aspirin and Fish Oil) 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
Shaping the future...

• Science

• Industry

• Patients

• NHS

‘... 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’
International Clinical Trials Day
20th May

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

- Science
- Industry
- Patients
- NHS
Shaping the future...

• Science
• Industry
• Patients
• NHS
Shaping the future…..

- Science
- Industry
- Patients
- NHS
Objective
To assess the impact of electronic health record (EHR) implementation on primary care diabetes care.

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.

Conclusion
Implementation of a commercially available EHR in primary care practice may improve diabetes care and clinical outcomes.

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

- 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

Courtesy of G Hall, University of Leeds
Shaping the future...

• Science
• Industry
• Patients
• NHS
Innovation & research

Local ownership

Research questions

Test ideas: study delivery

Dissemination across area

Service improvement

Patients & research community

Clinical Research Network

NHS orgs

Academic Health Science Network
R&D management
R&D management

- service
- patient-facing
- known for leading-edge use of data in the NHS
R&D management – data informed
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

<table>
<thead>
<tr>
<th>Questions relevant to clinicians &amp; patients?</th>
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<tbody>
<tr>
<td>Low priority questions</td>
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<tr>
<td>Important outcomes not assessed</td>
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<tr>
<td>Clinicians and patients not involved in setting research agendas</td>
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<tr>
<th>Appropriate design and methods?</th>
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<tr>
<td>&gt;50% of studies designed without reference to SRs of evidence</td>
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<td>&gt; 50% of studies insufficiently reduce biases</td>
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<th>Accessible full publication?</th>
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<tbody>
<tr>
<td>&gt;50% of studies never published in full</td>
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<tr>
<td>Biased under-reporting of studies with disappointing results</td>
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<th>Unbiased and usable report?</th>
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<tr>
<td>&gt;30% of trial interventions not well described</td>
</tr>
<tr>
<td>&gt;50% of study outcomes not reported</td>
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<tr>
<td>Most research not interpreted with reference to other relevant evidence</td>
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R&D management

• secondments to industry, academia & clinic

• element in general manager training

• managers and researchers

Health Services and Delivery Research (HS&DR) Programme

http://www.nets.nihr.ac.uk/programmes/hsdr
R&D management

Pattern of care and impact of participation in clinical studies on the outcome in ovarian cancer
R&D management – system pilots

**INVENTION**
- Creation
  - new things
  - new ideas
  - new techniques
  - new approaches

**EVALUATION**
- Assessment
  - new things
  - new ideas
  - new techniques
  - new approaches

**ADOPTION**
- Uptake
  - new things
  - new ideas
  - new techniques
  - new approaches

**DIFFUSION**
- Spread
  - new things
  - new ideas
  - new techniques
  - new approaches

**Basic Research**
- MRC & Charities

**Applied Research**
- NIHR

**Commissioning**
- NHS Commissioners

**Patient Care**
- Providers of NHS services

**AHSC**
- Better Quality
- Better Value

**AHSN**
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. …….”

http://www.nihr.ac.uk/files/pdfs/Promoting%20Research%20Active%20Nation_NIHR%20Strategic%20Plan_May%202014.pdf
Research

• for all

• informed by data

• focused on patient outcomes

• delivering economic benefit

• managed
Research – the way we provide best care