

Working with industry – Why bother?

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Research links with industry – why bother?

- Participate in drug and device development and evaluation
- Become involved in better treatments for existing and future NHS patients
- Generate income for reinvestment for future research or facilities
- Training
- Publications



Perspectives on the Pharmaceutical Industry

- **Biggest funder of medical R&D in the UK**
- **Provides access to leading edge therapies**
- **Helps keep NHS at forefront of medical care**
- **Contributes to national wealth**

Perspectives on the Pharmaceutical Industry



- Instrumental in “medicalisation” of society
 - A pill for every ill
- Secretive/conceals information to protect market position
 - Non disclosure of clinical trial data
- Distorts medical literature and opinion
 - Ghost writing of leading articles.
- Innovation crisis

Today's presentation

- The “health and wealth” agenda
- Industry drivers and requirements
- Industry trials in the NHS
- Challenges and benefits of working with industry
- Cooksey Review

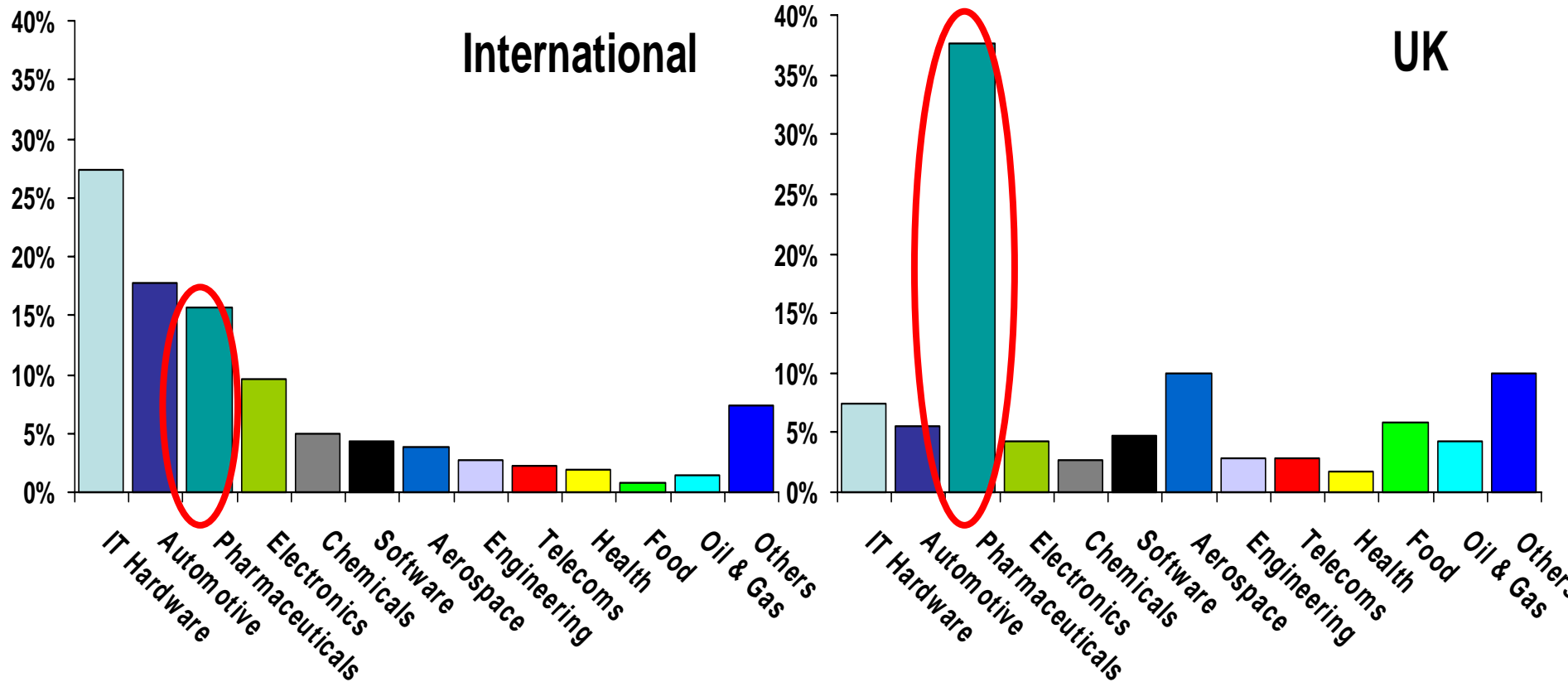
The Government is determined to make the UK the best place in the world for health research, development and innovation.

The NHS contribution to health research is a centrepiece of the Government's ambition to raise the level of R&D to 2.5% of GDP by 2014

Patricia Hewitt, January 2006



R&D By Sector



Pharma industry contribution to UK R&D

- **Leading industrial provider of research base in the UK**
- **£3.3 billion in 2006**
- **40% on clinical research**



Strengthening Clinical Research



department for
education and skills

Science and innovation:
working towards a ten-year
investment framework



National Institute for
Health Research



Better health through
partnership:
a programme for action

RESEARCH FOR PATIENT BENEFIT WORKING PARTY

FINAL REPORT

*"For us, science and research constitute a
front-line service, as they too, reduce distress
and pain and save lives".*

(Dr John Reid, Secretary of State for Health, 22 March 2004)

Bioscience
2015

Improving National Health,
Increasing National Wealth

A Report to Government by the
Science Innovation and Growth Team



A shared vision:

- To establish the position of the UK as a world leader in clinical research by harnessing the power of the NHS
- To benefit the public and patients by improving national health and increasing national wealth
- To work effectively with all partners, including **Industry**

Budget: March 2004



£100m increase in NHS R&D funding by 2008

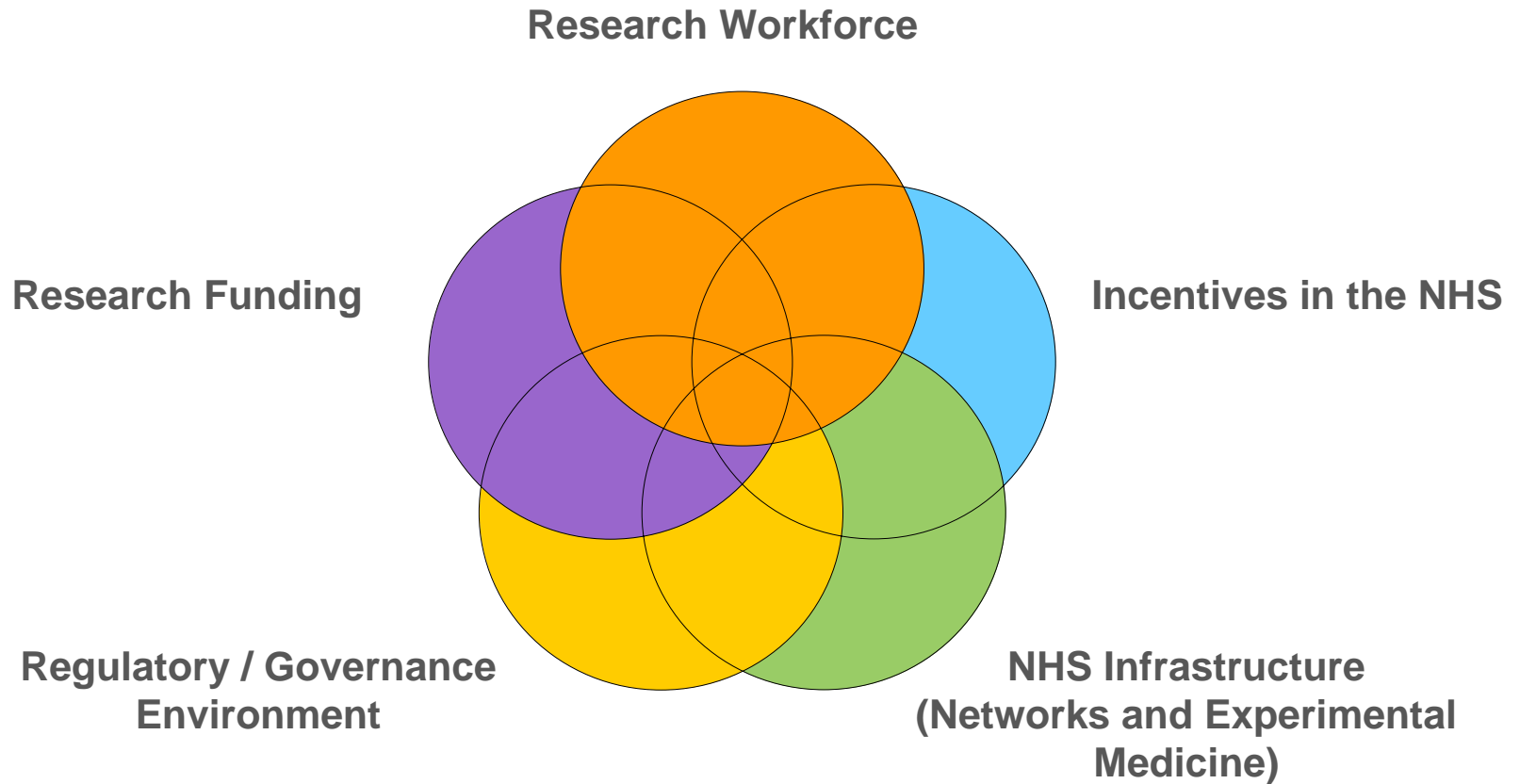
**-bring combined budget for medical research to £1.2bn
-purpose will be to achieve effective and efficient translation of scientific advances into patient care**

UK Clinical Research Collaboration (UKCRC)

- Established 2004 to re-engineer environment
- Partnership between public sector, private sector and patients **igniting our potential**
- Vision
 - to establish the position of the UK as a world leader in clinical research by harnessing the power of the NHS
 - to benefit the public and patients by improving national health and increasing national wealth



UK CRC Workstreams





www.ukcrc.org.uk



Best Research for Best Health: A New National Health Research Strategy

*The NHS contribution to health research in
England: a consultation*



Consultation 2005

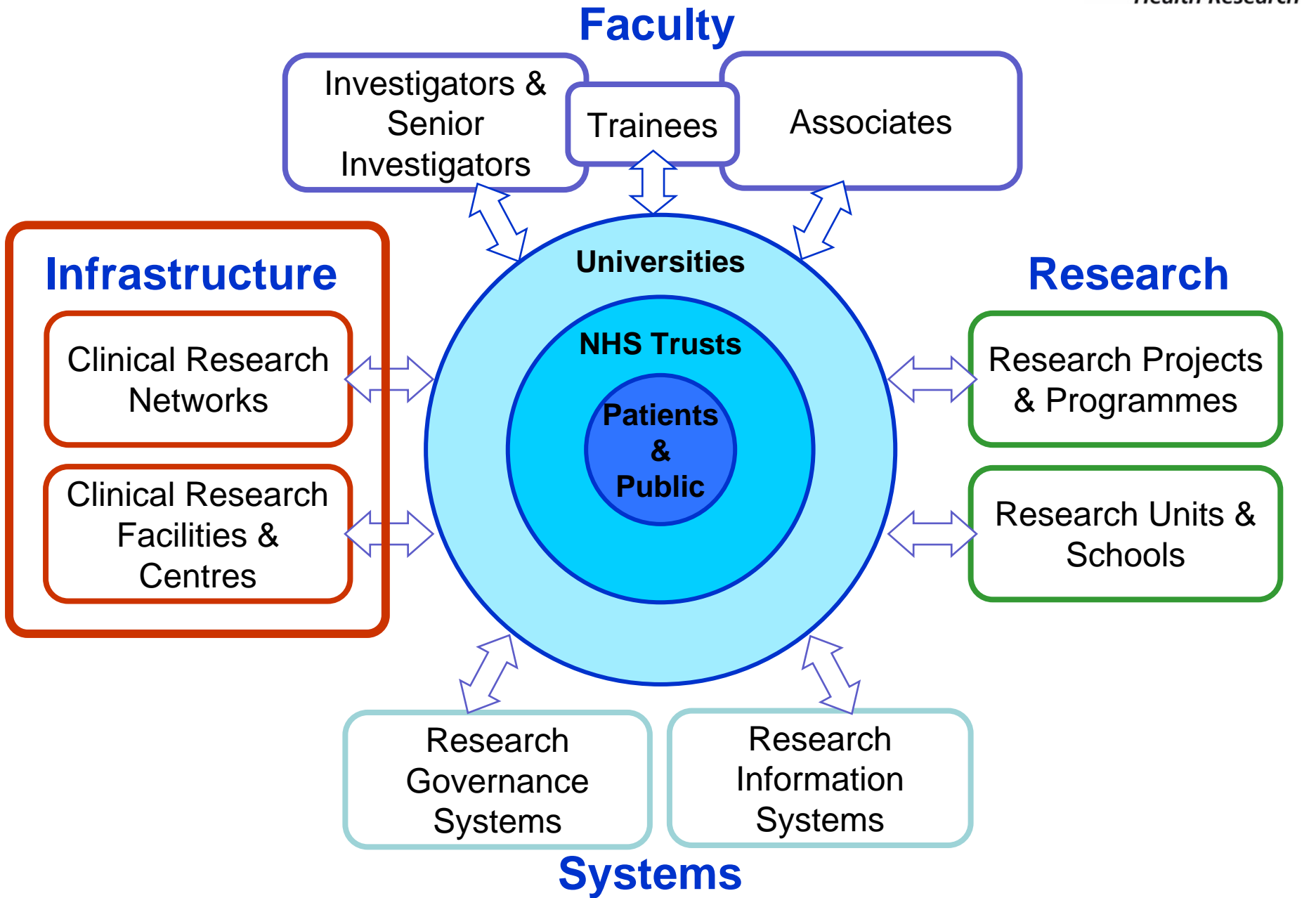


Best Research for Best Health

A new national health research strategy



New Government Strategy 2006



Best Research for Best Health: Delivering for Industry

- **Vibrant, innovative academic research base**
- **Customer focussed interface with NHS – access to large population in unified health system**
- **Streamlined system reliably delivering high quality data with rapid access to patients at reasonable costs**
- **Motivated, well-trained research workforce, with dedicated time for research**
- **Internationally respected data and systems for governance and protection of patients**
- **Ethical access to NPfIT data to support research**

Clinical Research Location Selection: Key Factors



McKinsey Report 2005

- Strategic Location
 - Reputation of regulatory authority, opinion leaders, market potential
- Quality
 - Of data and Clinical / scientific reputation of physicians
- Performance
 - Timely
 - Reliable
 - Cost effective

Summary of UK Position –

• Strategic importance

- Uptake of new drugs is usually good after having done clinical trials, e.g., in Italy, France or Germany. This is not true for the UK, where the uptake of new drugs is very low, even if the trials have been conducted in the UK.

• *Pharma executive*

• Quality

- The UK is losing its clinical trials expertise. There are not enough experts being trained and not enough training positions.

• *Pharma executive*

• Time

- The key drawback to conducting clinical research in the UK today is the speed of the approval process: the MHRA, COREC and centre R&D approval.

• *Devices executive*

• Reliability

- NHS organisations and clinicians have an appalling track record for failing to deliver results as agreed in commercial clinical research.

• *Pharma industry stakeholder*

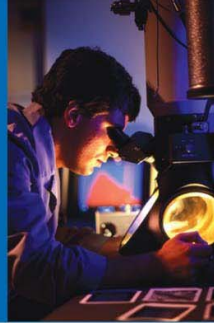
• Cost

- Trust managers use clinical research funding as a way to raise extortionate funds. There are up to 4x differences in costs for the same trial across UK sites.

Biotech industry stakeholder



The Association of the
British Pharmaceutical Industry



R&D Start Up Times

2007 (7 companies)

Average time from notification to R&D sign off = **110.8 days** (range 2 to 309 days)

Average time from R&D sign off to first patient / visit = **61.9 days** (range 1 to 326 days)

Total average time from notification to first patient / visit = **172.7 days** (approx 5.76 months)

2006 / 2005

Average time from notification to R&D sign off = **65.8 days** (range 4 to 439 days)

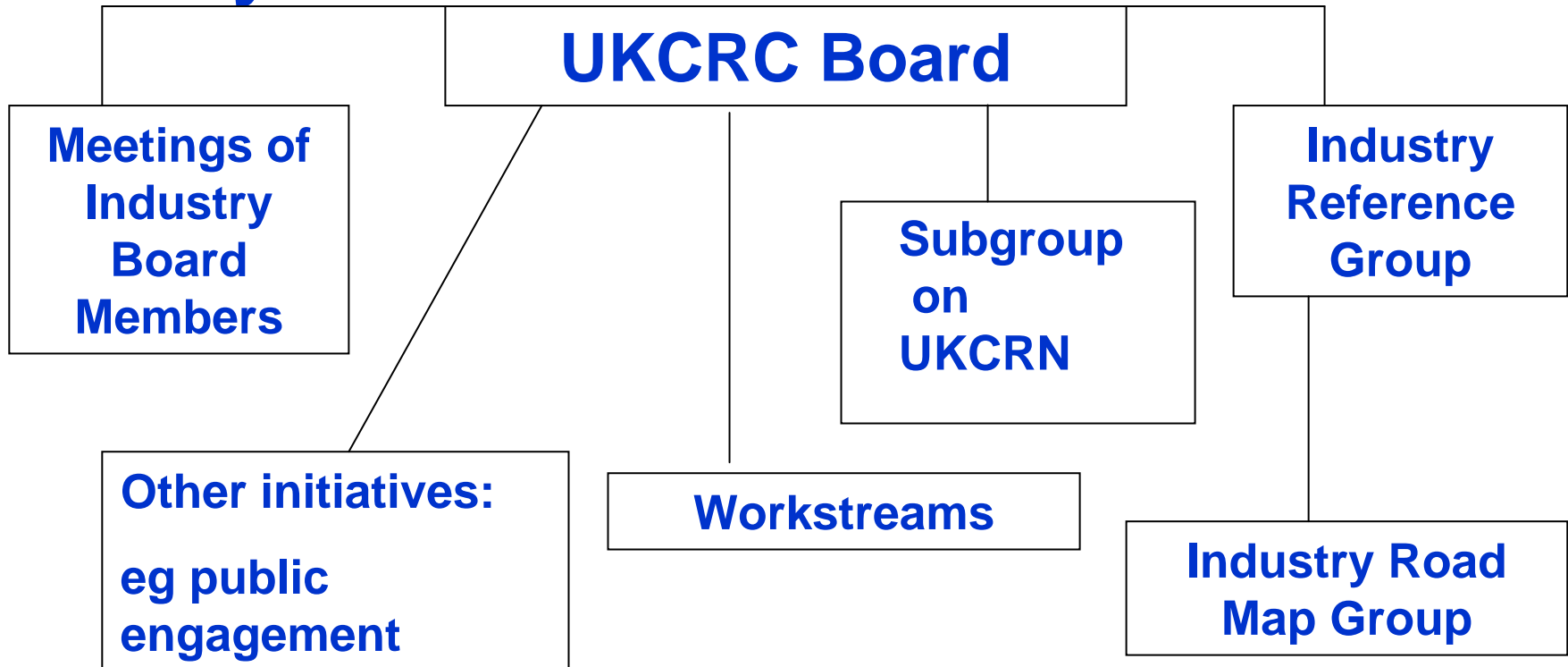
Average time from R&D sign off to first patient / visit = **34.7 days** (range 1 to 150 days)

Total average time from notification to first patient / visit = **100.5 days** (approx 3.35 months) (2005 = **116 days**)

Clinical Research – Govt / Industry / Broader Stakeholder Groups

- Ministerial Industry Strategy Group
- Ministerial Medical Technology Strategy Group
- NIHR Medical Device Clinical Research Working Group
- UKCRC Industry Groups

Industry Involvement in UKCRC – All Levels



Feedback via Trade Associations

UKCRC Industry Roadmap Group goals facilitating industry trials in networks

Focus on:

- **Better feasibility data**
- **Speed of commitment**
- **Speed of trial set-up**
- **Speed of delivery**
- **Quality of data**
- **Consistency of agreements & arrangements**
- **Cost of service**
- **Building up the basis for partnership working**
- **Metrics**

UKCRN – Services to Industry

- **“One stop shop” for access to experts and specialist experience**
- **Standing Confidentiality Agreements covering company and UKCRN networks to expedite consultation**
- **Rapid response mode initial feasibility opinion**
- **Highly detailed site specific capability assessment**
- **Routine use of model Clinical Trial Agreement**

UKCRN – Services to Industry

- **Single costing template for multi-centre studies**
- **Central sign off for R&D at a national level for multi-centre trials**
- **“Research Passport” for honorary research contract agreements**
- **Network monitoring of recruitment and performance management**

Collaboration

1. [n] act of working jointly



**working
together**

Collaboration

1. [n] act of working jointly
2. [n] act of cooperating traitorously with an enemy.

Biomedical research links with industry – some challenges

- Cultural differences
- Degree to which objectives of industry and NHS/academia are seen to be aligned
- Public/patient perspectives on industry
- Long term outcomes vs registration needs
- Opportunity for meaningful user engagement
- Clarity on “rules of engagement”, governance

Contract vs Collaborative Research

- Industry wants to work with NHS on both
- Early interaction is being encouraged
- Phase III trials challenges
 - participating countries decided by company HQ
 - protocol may be fixed before UK receives
 - design constrained by regulations
 - speed is of the essence

Cooksey Review - Process



- Extensive **consultation**
- **Visits** to health research institutes and research funders in UK, Europe and USA
- Close working with all **stakeholders**
- **Reported** to Government in time for 2006 Pre-Budget Report
- **Announced** by Chancellor as part of Pre-Budget Report on 6 December 2006
- Government has **welcomed** the review and will work to **implement** its recommendations

Cooksey Review - Context

Increasing determination in the UK to:

- Ensure **swift translation** of developments in basic biomedical research into benefits for patients and the public
- Increase the volume of **applied health research** to underpin effective and efficient public services
- Harness the **potential of the NHS** as a platform for applied health research to improve the nation's health and increase the nation's wealth

Cooksey Review of UK Health Research



HM TREASURY

Findings:

- The UK has strong basic research
- But insufficient translation of the results of basic research into applied research
- And insufficient translation of the results of applied research into practice in the NHS

Government Action:

- A single strategy for Government-funded health research to join up basic, translational and applied research
- Stronger co-ordination of research funded by the MRC and the NHS
- Industry as a key partner with a seat on the Board of the new Office for Strategic Co-ordination of Health Research

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Summary

- Government policy – health and wealth agenda
- Industry and NHS/academia have overlapping agendas
- Effective research links require
 - Clarity on objectives, roles and responsibilities
 - Clear “rules of engagement”, including governance
 - Mutually respectful relationships
- Aim – a symbiotic relationship of which patients are the ultimate beneficiaries