

Challenges and Opportunities in the UK Research Environment

A perspective from the makers of medicines

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Challenges to UK Life Sciences

- Slow start up of trials
- High cost / expensive
- Good quality but other countries supply good quality with faster start up and lower costs
- Uptake of innovative medicines
- Pace of change
- Pipeline pressure
- Funding

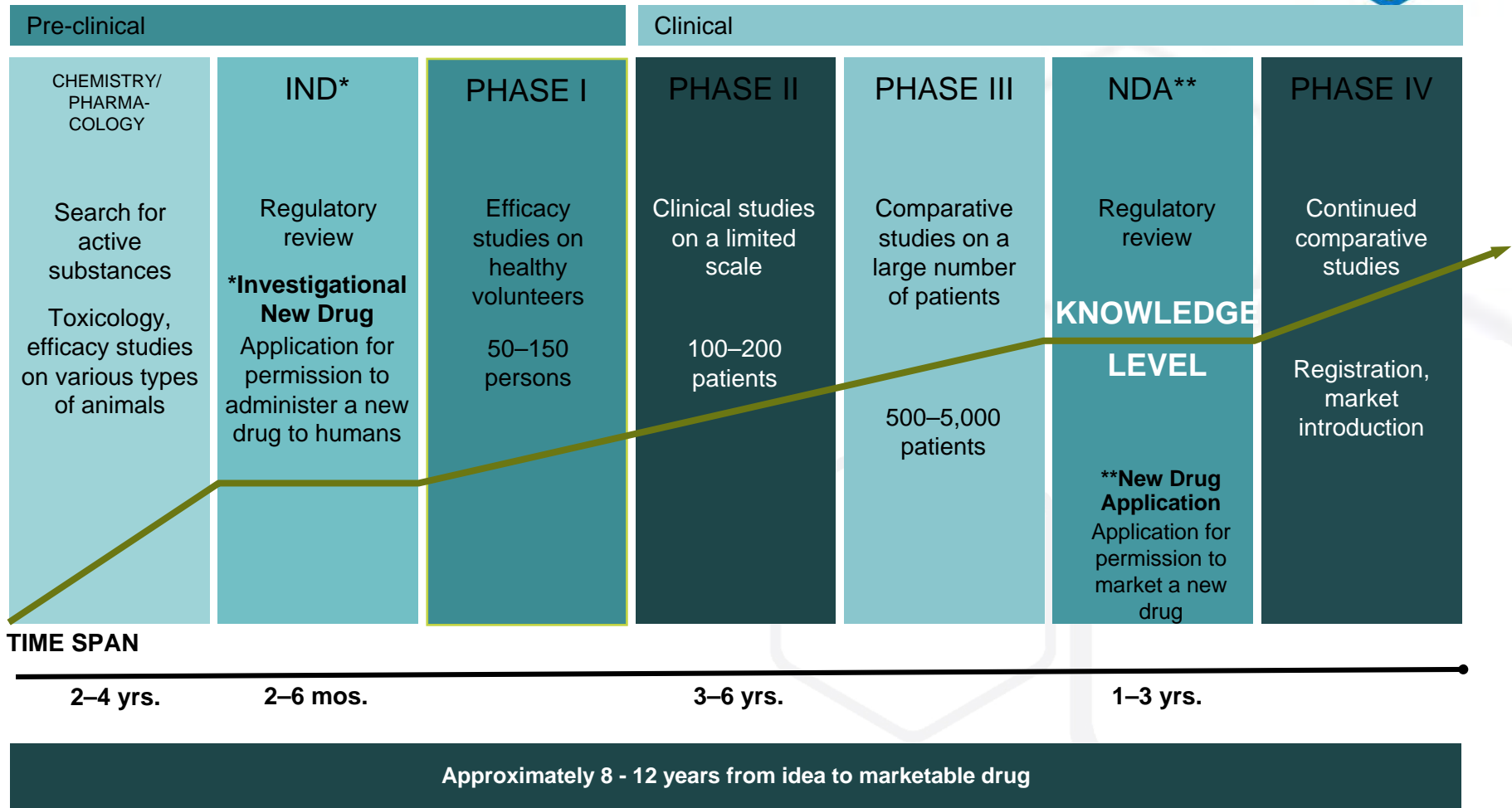


Opportunities in Life Sciences

- Early phase drug discovery & late phase clinical trials
- Collaboration
- Academic base
- Real world data
- Personalised medicines strategy
- NHS: Champion of Innovation



Got a spare half a billion?



Historical:

“Clinical Research in the UK” (McKinsey Report – August 2005)

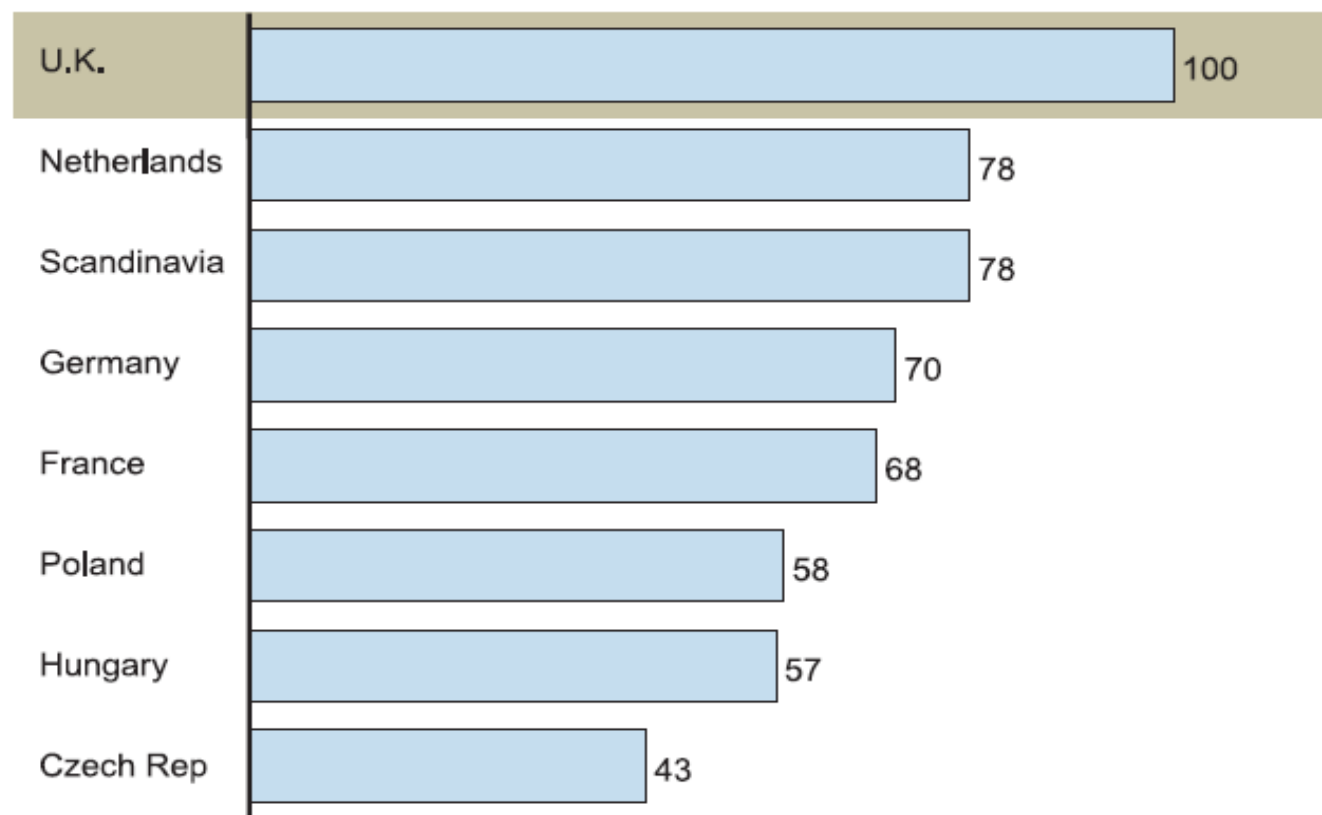
High Cost



EXHIBIT 12: COST PER PATIENT COMPARISON

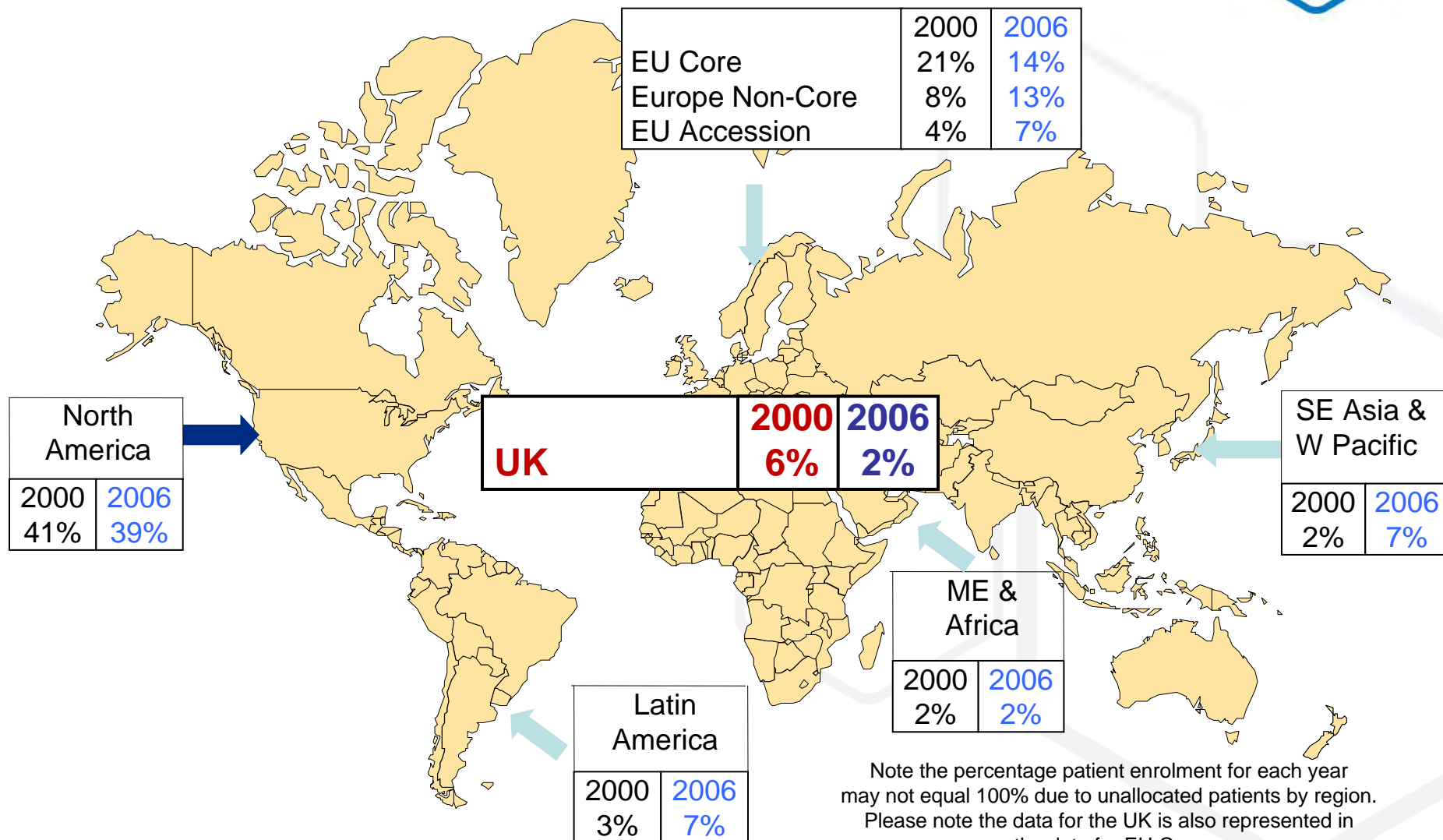
Comparison of phase 2/3 costs per patient, 1995–2002

U.K. = 100 base



Source: Parexel R&D Statistical Source Book, 2004/05

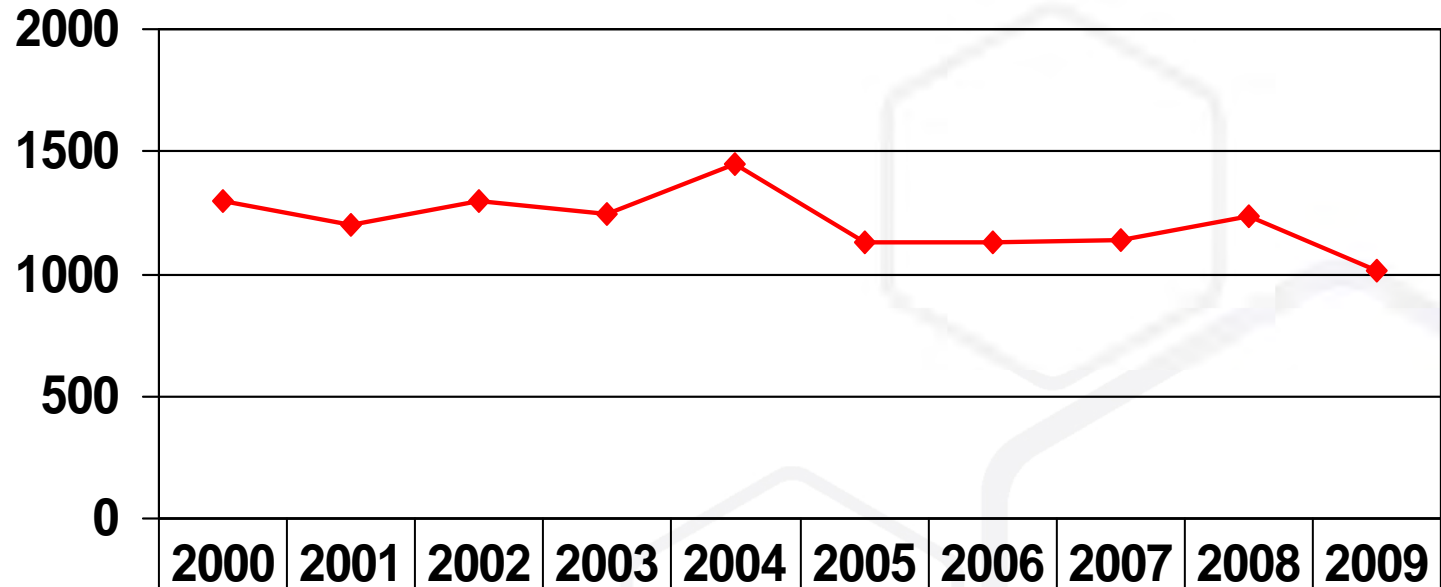
Historical: Global Patient Enrolment 2000 vs 2006 UK declines from 6% to 2%



Note the percentage patient enrolment for each year may not equal 100% due to unallocated patients by region. Please note the data for the UK is also represented in the data for EU Core



UK Clinical Trial numbers

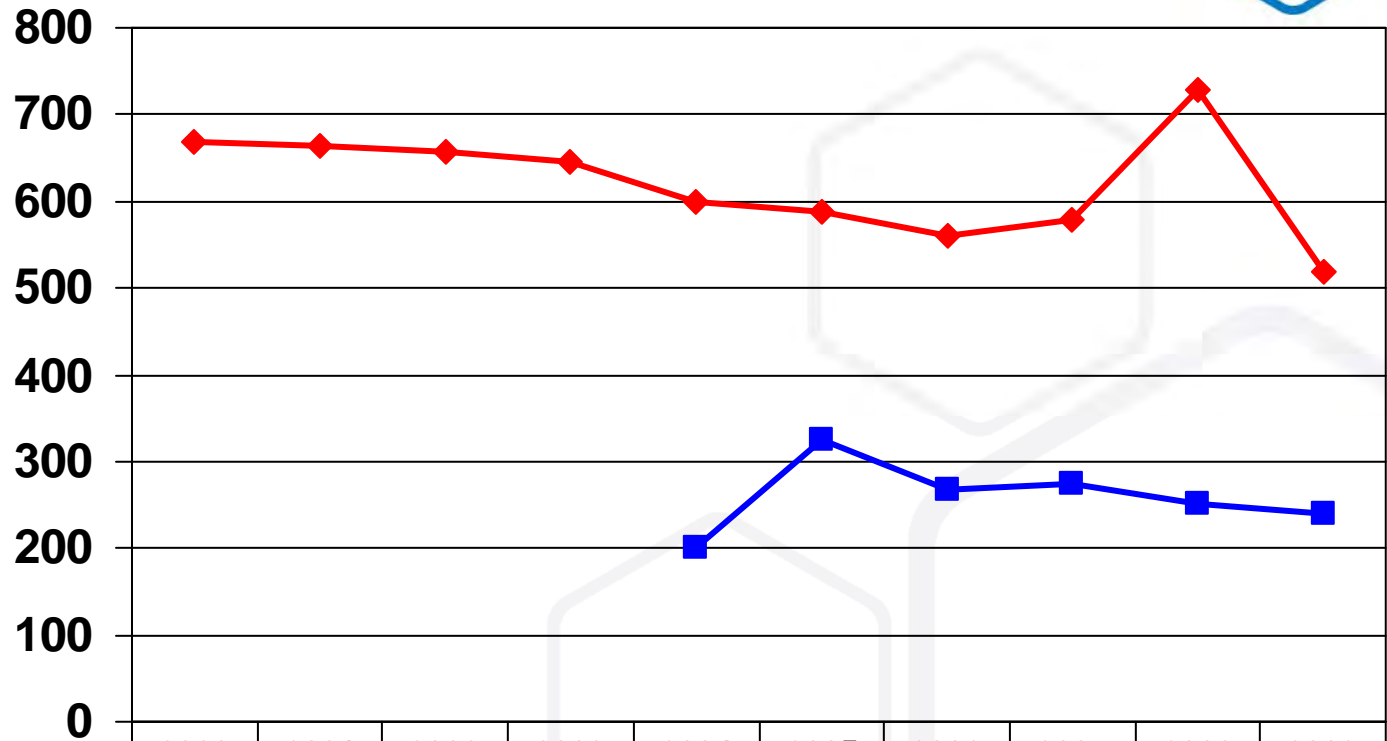


◆ Trial numbers	1300	1203	1296	1244	1452	1132	1125	1141	1240	1014
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◆ Trial numbers

Data supplied by the MHRA

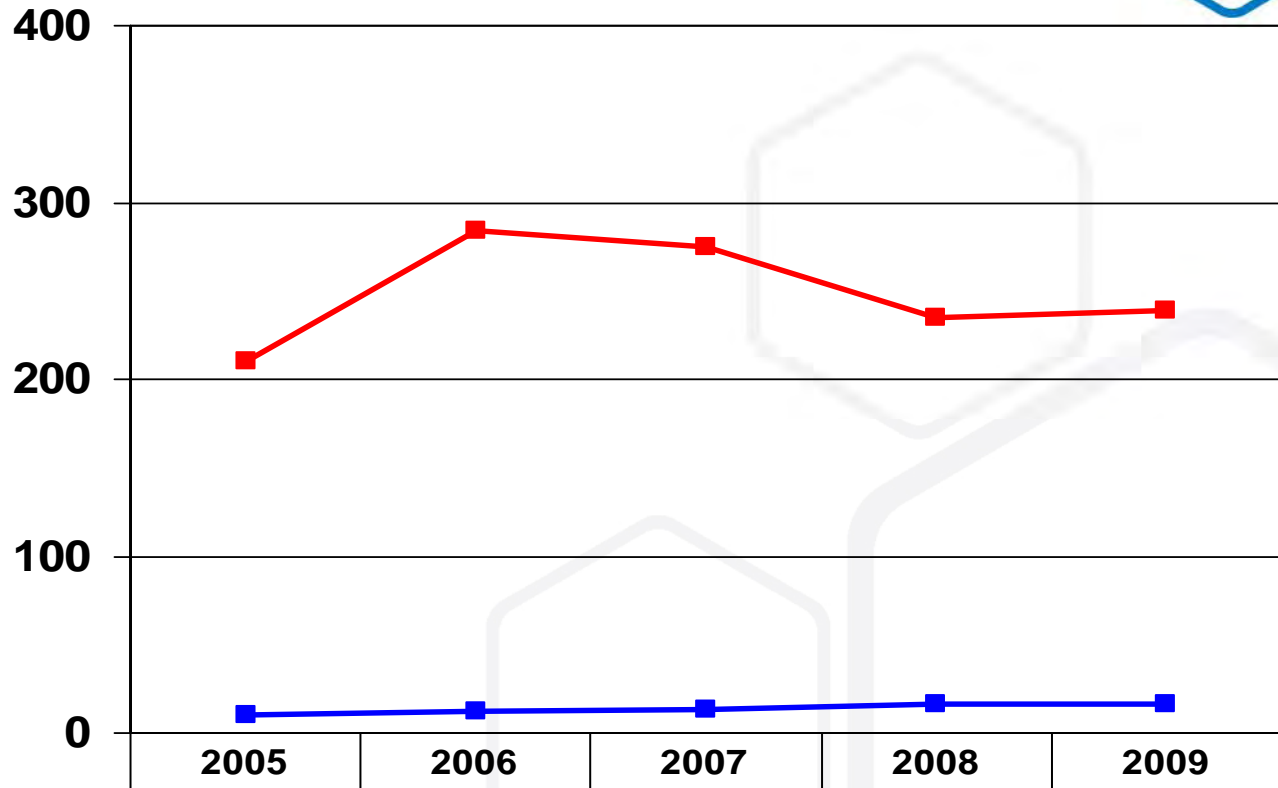
UK Commercial applications received



Commercial Phase 2/3/4	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Commercial Phase 1										

Data supplied by the MHRA

UK Non-Commercial applications received



—■ Non-Commercial Ph 2-4	210	284	275	235	239
—■ Non-Commercial Phase 1	10	12	13	16	16

Data supplied by the MHRA



Continuing issues – time; cost; quality

- Lack of parallel working
- Some Trusts still carrying out their own scientific review
- No incentive for Trust/HB CEOs to champion research and recruitment targets
- Some PCTs/HBs respond within 48 hours so why not all?
- Faster start-up times are achievable but extra human resource and financial costs are considerable
- MHRA Inspectors often find inadequate site oversight
- Some good centres now deteriorating and compliance issues developing
- Variable staffing levels / expertise within R&D Offices

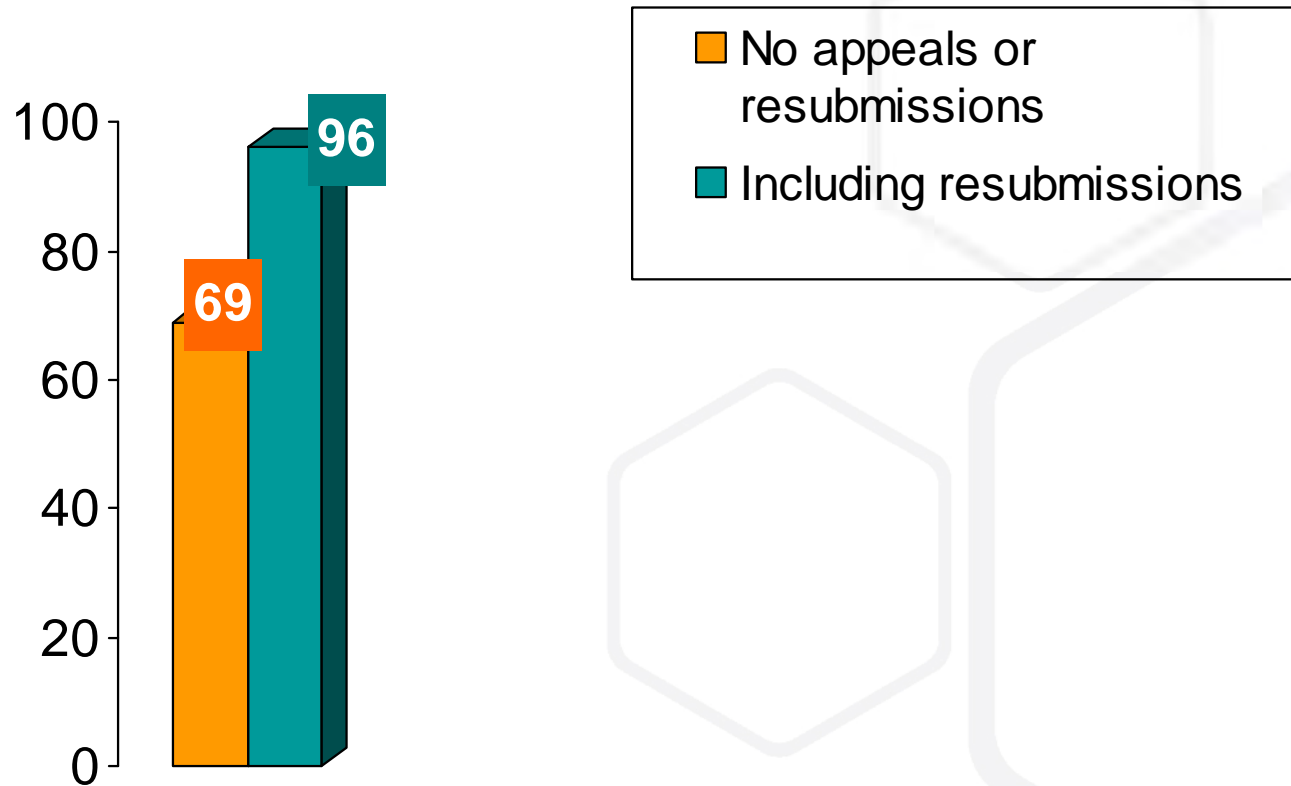


“Snap-shot” of Industry's experience of the UK Clinical Research environment

(2009 – 11 companies; 2008 – 14 companies)

**For the year 1st April 2008 to 31st March 2009
(i.e. actual 1st patient / 1st visit within that period)**

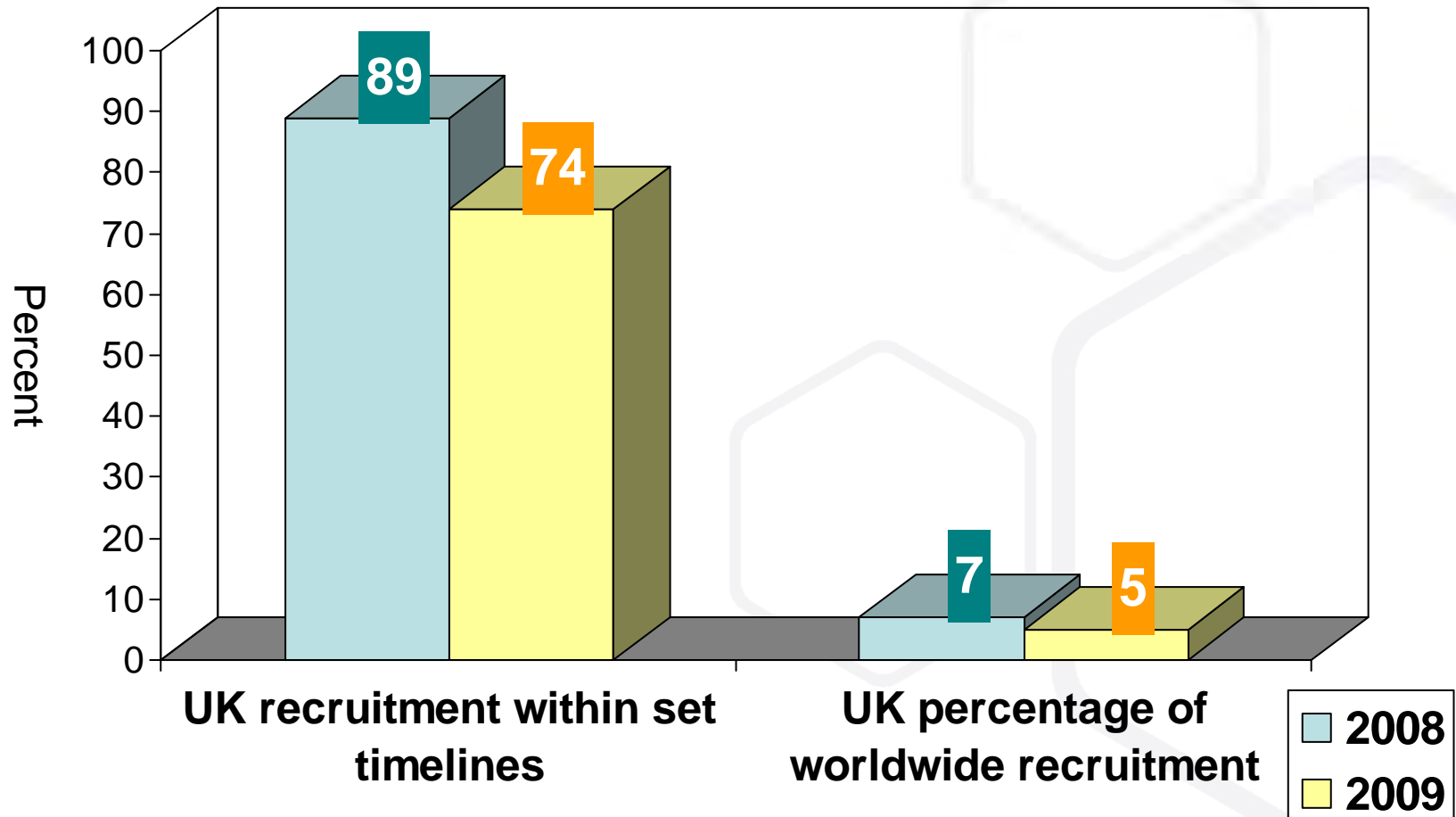
What is the time from Ethics submission to the final Ethics approval?



International studies involving UK sites:

What was the percentage UK recruitment within your set timelines?

What was the percentage worldwide recruitment of UK patients?





Snapshot of industry experience of conducting research in the UK

Compared to the other major Western European countries the UK takes:

- Longer to get approvals, set up and run trials
- Once up and running, overall number of patients per centre delivered is lower than other Western European countries as we have less time to recruit
- The % of sites that recruit no patients is high – affecting overall productivity figures
- Many sites do not deliver the agreed target
 - Individual site recruitment figures – UK only delivers % of the expected target number of patients
 - Expected targets are the ones agreed with the sites at the outset based on feasibility
- Sites are taking longer than contractually agreed to enter patient data post visit

Solutions & Opportunities



Solutions for attracting research



- NHS still has a good reputation
- Follow best practice – good centres have an operational team separate from the intellectual team that considers the science
- Use of Clinical Research Networks – more activity from NIHR CRN Coordinating Centres
- Recognise need for rapid feasibility to maintain competitiveness
- Model Clinical Trial Agreements (mCTAs)
- Costing Template
- Integrated Research Application Service (IRAS)
- Coordinated System for gaining NHS Permissions (CSP)
- Build on NRSS progress
- NIHR Research Support Services – aim to professionalise R&D offices
- NIHR Office for Clinical Research Infrastructure (NOCRI) established



What would industry like to see?

- Commitment from Trust/HB CEOs to engage in the delivery of the implementation plan and in driving performance in their Trusts/HBs
- Equal prioritisation given to commercial trials
- National standards for governance which will improve quality, speed and efficiency of research & research processes
- Consistent delivery in clinical research performance across Trusts/HBs, driven by appropriate incentivisation
- Single process for Network and non-Network studies
- NHS organisations to continue to increase their level of participation & performance in hosting research funded by non- commercial and commercial research funders
- Quality Accounts to include the number of patients recruited to clinical research
- Specific undertaking to raise the awareness of clinical trials and the value they bring to the Health of the Nation within the UK community.



What success would look like

Metric to be measured	Target to be met
Time from Trust protocol receipt to first patient/first visit (FPFV); including time for gaining NHS permission	<ul style="list-style-type: none">• 80% in less than 10 working weeks; in parallel with MREC approval• 80% in less than or up to 30 days to gain NHS permission
Percentage of interventional studies that recruited to agreed time and to target	<ul style="list-style-type: none">• >80% recruited to time and target
Number of patients recruited in the year into industry partnership interventional studies	<ul style="list-style-type: none">• Doubling of patients recruited in industry sponsored trials by the end of 2010• <2% of studies recruiting 1 or fewer patients

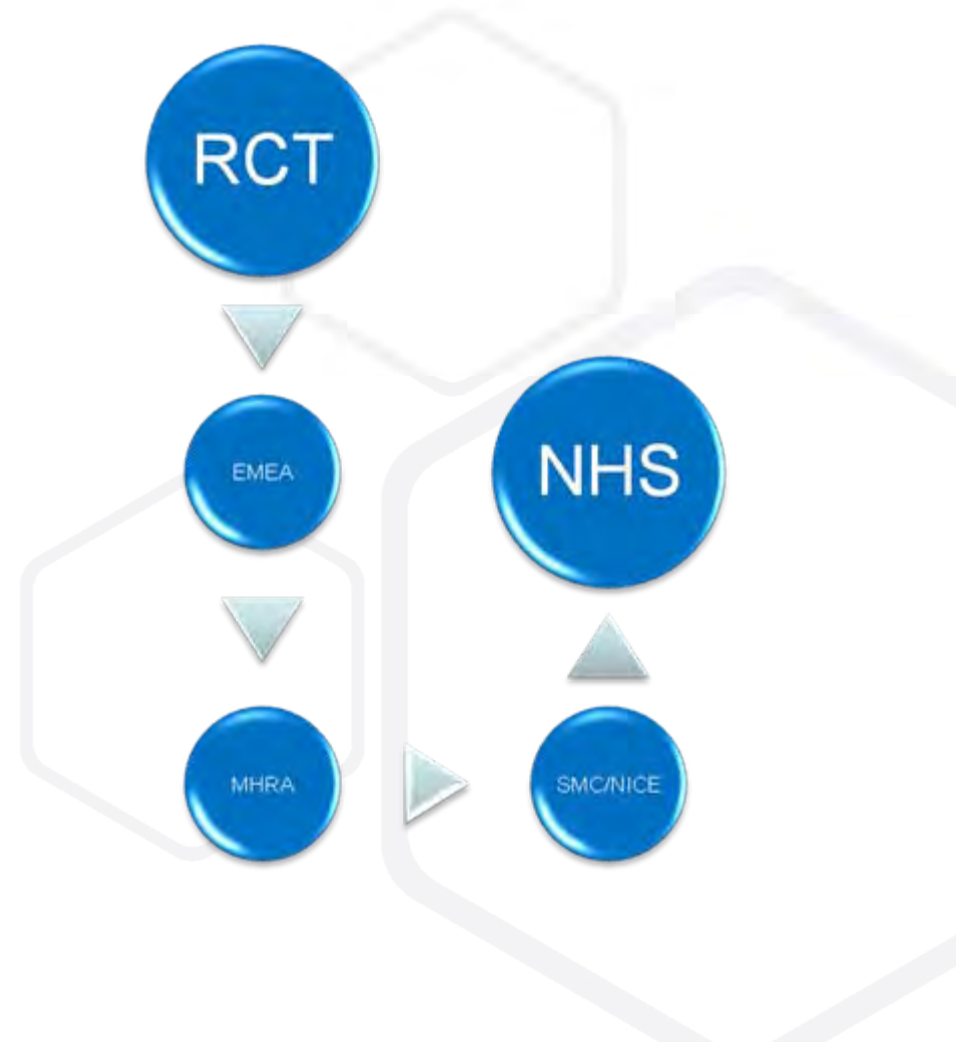
Collaboration

- OLS
- NRSS
- LiSAB
- SAHSC
- Pharmacy Collegiate



Real World Data

- Reimbursement environment is changing
- RCT RIP?
- Are we asking the right questions for the SMC, NICE & NHS?
- Value based pricing looms
- Proving real world value becomes crucial
- Coverage with evidence development





What are the right questions?

In addition to the clinical data:

- patient-reported outcomes
- quality of life improvements
- health related quality of life impact on carers and families
- costs to patients
- benefits and non-direct NHS costs
- Impact on NHS service design
- Concordance
- Wastage



Use of new medicines

- Global investment environment
- Uptake lower than other markets
- Comparator choice
- Innovation pass
- Patient Access Schemes

A vision for the future

Improved patient outcomes due to access to innovative medicines and vibrant research sector

NHS receives and delivers increased value

IT infrastructure builds to support research

Patent Box and fiscal incentive

Cluster development

Investment in to the UK economy

Patient recruitment becomes part of culture

Research linked to better patient outcomes

Education sector supports life sciences development

