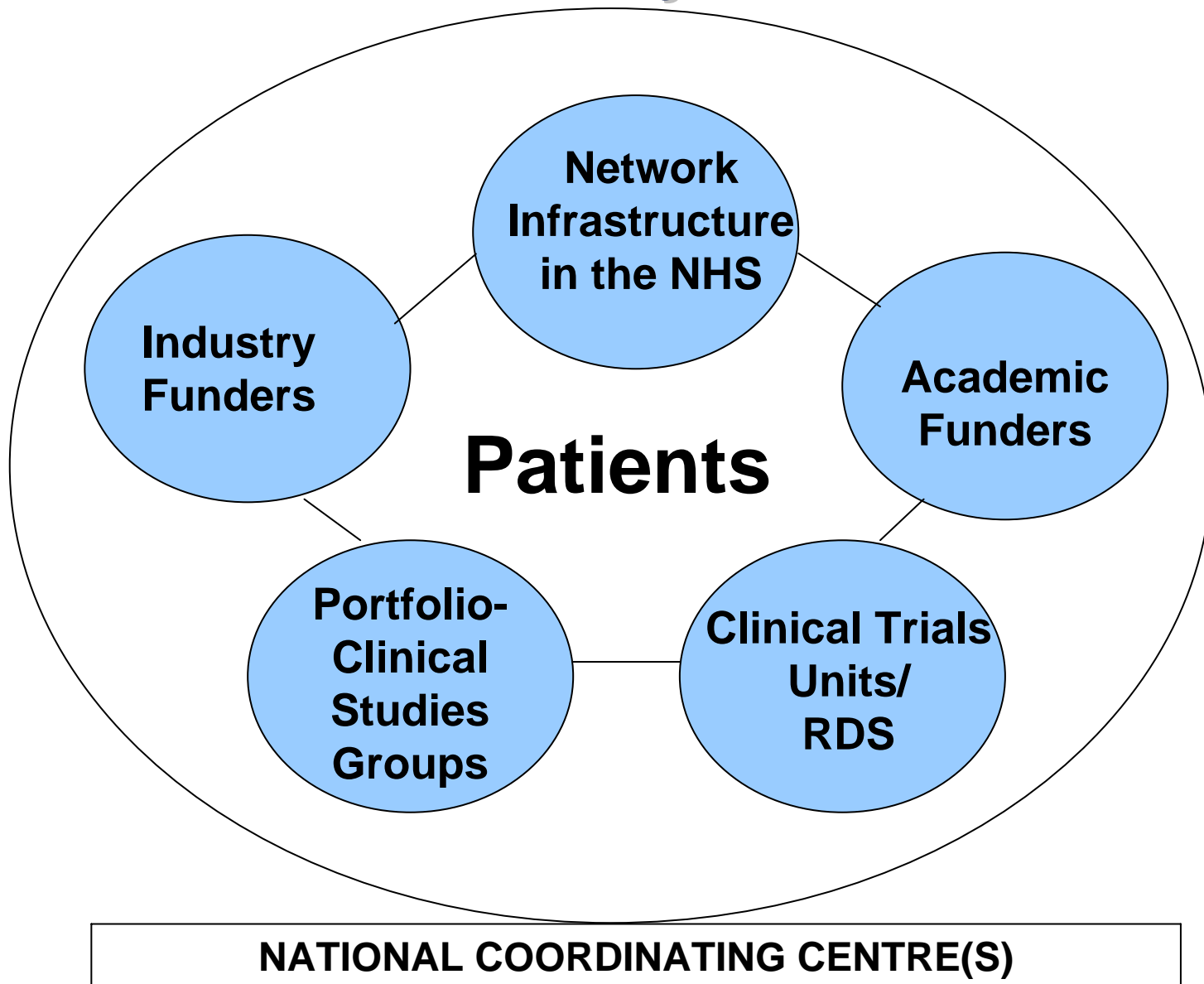


CCRN Open Meeting / Registered CTUs Meeting

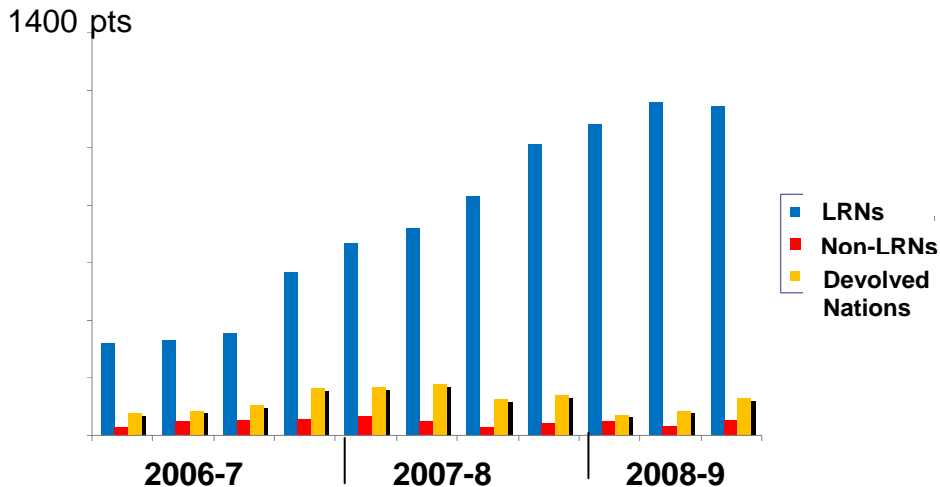
Future Challenges and Developments in Clinical Research Networks

Professor Peter Selby
Joint Director NIHR CRN
19 March 2009

'A Whole System'



Accrual by Stroke LRNs, Non-LRN areas and Devolved Nations



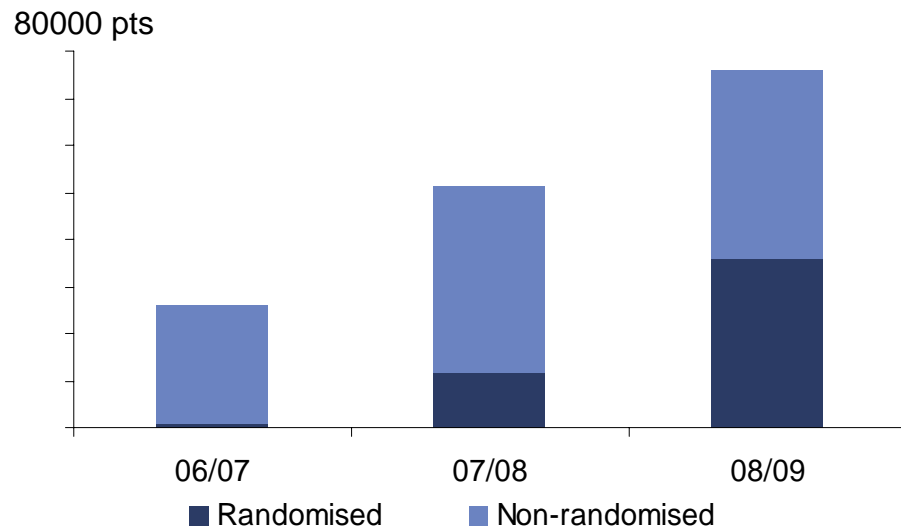
Topic CRNs

- All Topic CRNs ,CRN CC,PCRN &CCRN have now been reviewed by independent international panels
- All received positive outcomes (“impressive”, “outstanding”, “excellent”)

Primary Care CRN – 2006/8

- Well established
- Building portfolio
- Accrual growing (30% total portfolio)
- A nationally managed approach
- Links to School and MRC GPRF

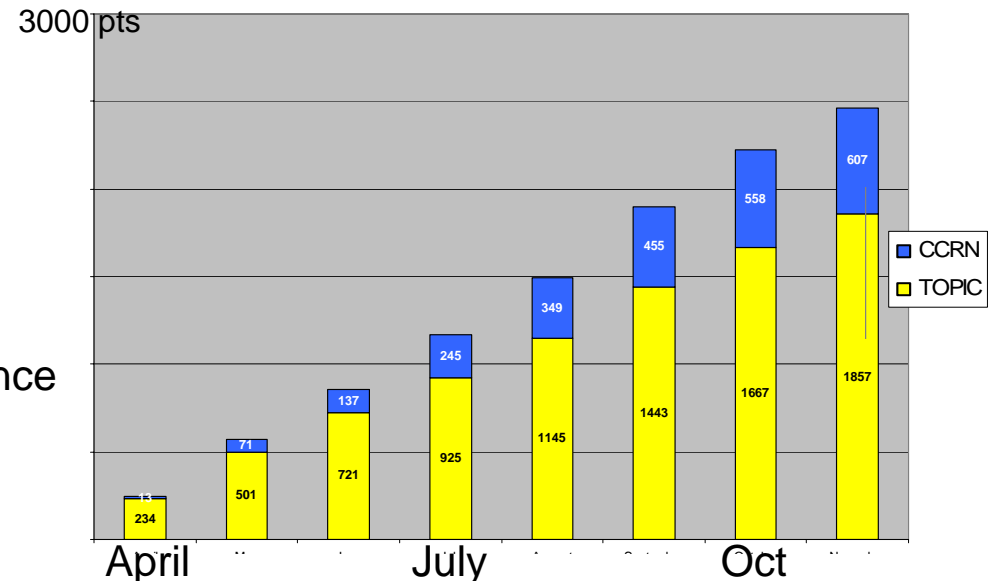
The Total Primary Care Accrual per Financial Year



Comprehensive CRN - 2007/8

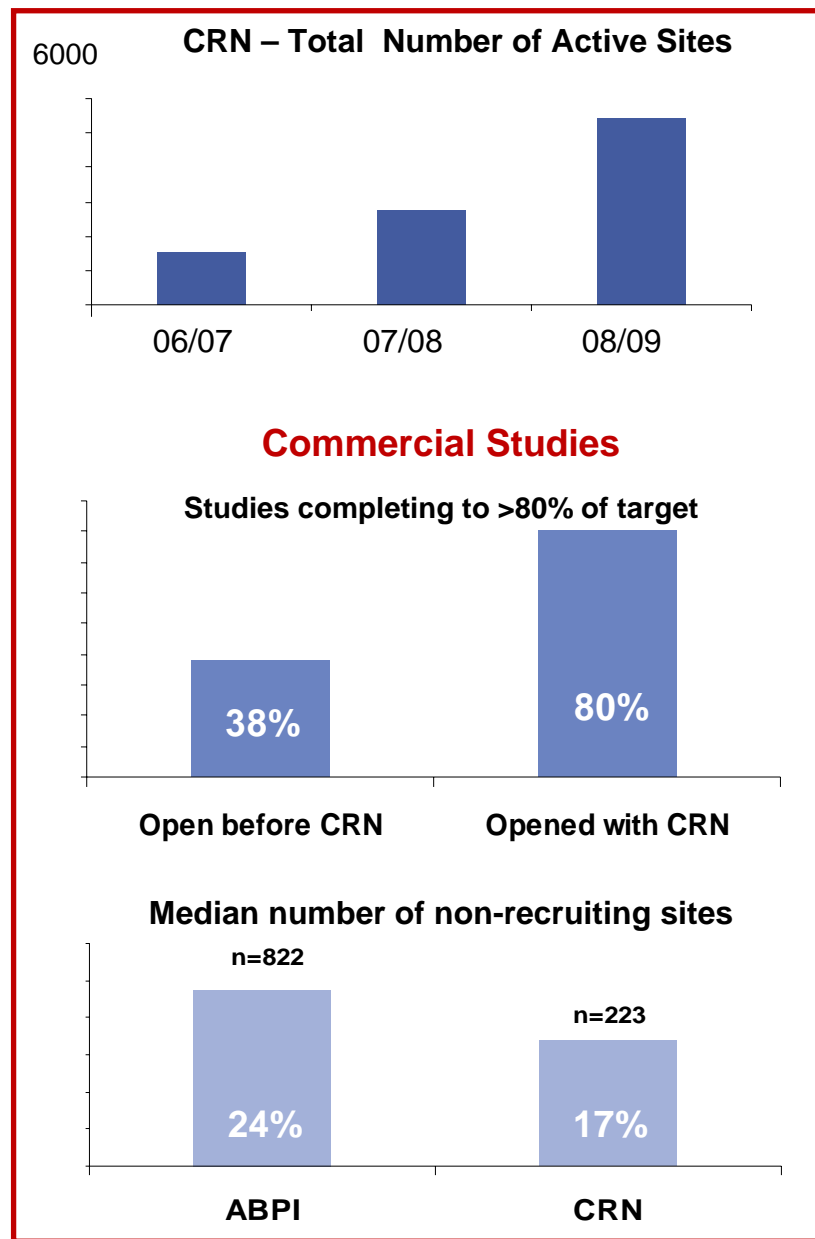
- Established ahead of schedule with every NHS Trust represented via 25 CLRNs
- Rapid overlapping phased approach
- Excellent leadership and engagement
- Unblocking blocks in research governance (CSP) and infrastructure

**Cumbria and Lancashire CLRN
April – Nov 2008**



CRN Review Criteria

	TCRN	PCRN	CCRN
Participation	•	•	•
Integration	•	•	•
Removing Barriers	•	•	•
Industry Collaboration	•	•	
Balanced portfolio	•	(•)	
Speed			
Accrual/Completion	(•)		
Patient Benefits	(•)		



Summary-so far

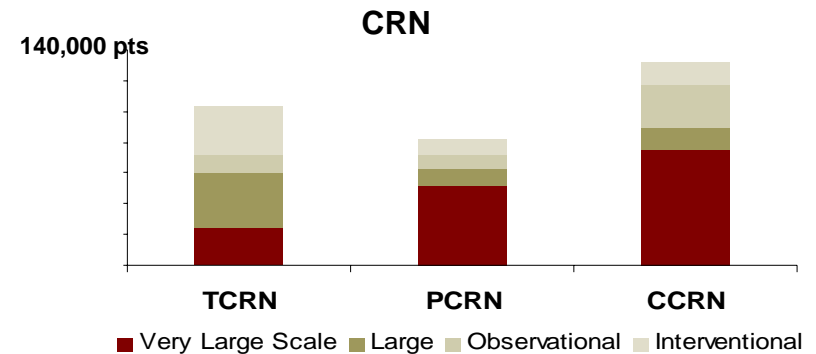
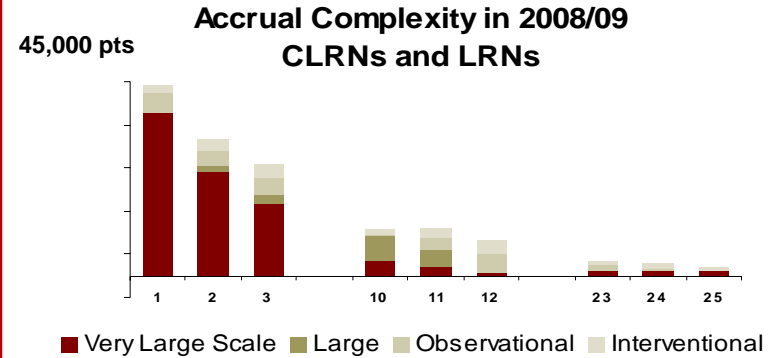
- Clinical Research Networks established and the six Topic CRNs are performing to high standards
- Topic CRN “model” proved to work well
- Patients remain central
- Progress with industry studies but more to do
- PCRN and CCRN set up ahead of schedule; already showing promise but models are different & more complex
- Rapid changes implemented – with broad (if incomplete) consensus
- Still work in progress, with many remaining problems; need to consolidate and focus upon measurable patient benefits

Key Challenges for 5 years

- **Deliver all CRNs to the same high standard and criteria**
- **Deliver complex projects (Portfolio, CSP, ABF)**
- **Realise industry expectations**
- **Reduce and manage bureaucracy - make research easier and more fun**
- **Increase NHS Trust Engagement**
- **Increase effective engagements of patients and the public**
- **NHS Operating Framework ambition**
- **Demonstrated benefits for patients, science and the economy**

Delivery Clinical Research Networks

- Management and integration of Topic, Primary Care & Comprehensive CRNs and Local Research Networks to ensure delivery
- CRN CC appointments
- Work with NIHR IS to specify Portfolio & CSP systems
- Activity Based Funding and Finance “Flows”
- ‘Closing the Loop’ – better data/used better



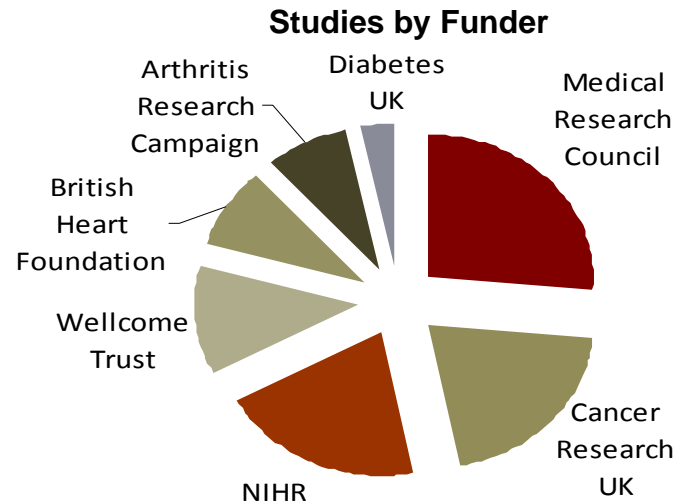
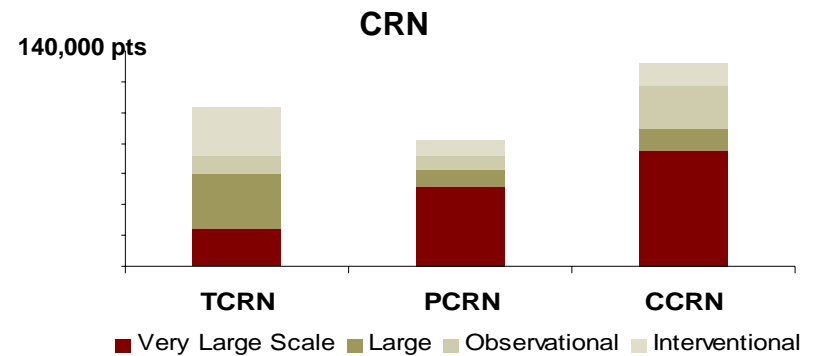
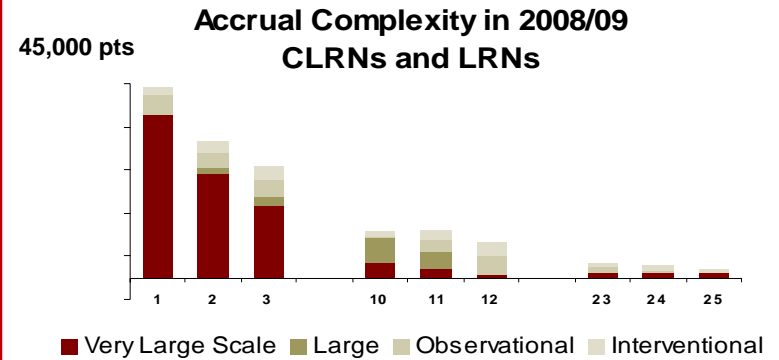
“CLOSING THE LOOP”

Utility of Information for stakeholders

- Patients
- Networks
- Funders
- Investigators
- Clinical Trials Units
- NHS Organisations
- Sponsors

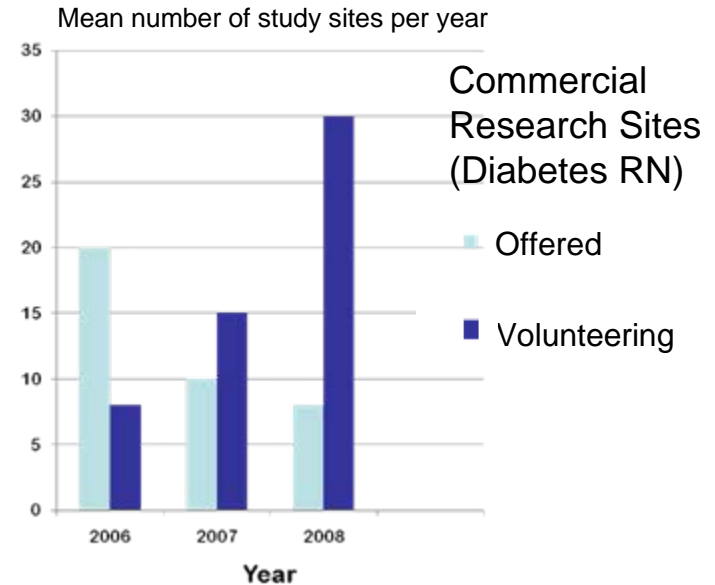
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Realising Industry Expectations

- Increasing engagement with Industry and NHS Trusts but more work needed
- Initial metrics are encouraging
- Focus on Comprehensive and Primary Care CRNs



New proposals

Industry Initiation Portfolio

- Open to all studies
- RM&G (CSP, Costing Template, mCTAs etc)
- Time limited (2 years)

Focus on Industry Priorities

- Mapping commercial need with CRN capability
- Focus on specialty, phase and specialist facilities leading to effective delivery

Reduce and Manage Bureaucracy: what CRNs can do/what others can do

Industry

Portfolio

Research Management & Governance

NHS Engagement

Patient and Public Involvement

Clinical Trials Units

Experimental Medicine

Workforce and Training

Information and Operating Systems

Communications

CSP Progress

Number of pre-applications received	201
-of which are commercial studies	16
Number of R&D forms validated	70
Number of studies granted NHS approval using CSP	3

Time to NHS Approval from R&D Form Validation		
Study 1	Multi-site	51 days (first site)*
Study 2	Single-site	39 days
Study 3	Single-site	15 days

* 82 day median time to NHS Approval from R&D Form Validation (ABPI metrics 2008)

NHS Engagement

Industry

Portfolio

Research Management & Governance

NHS Engagement

Patient and Public Involvement

Clinical Trials Units

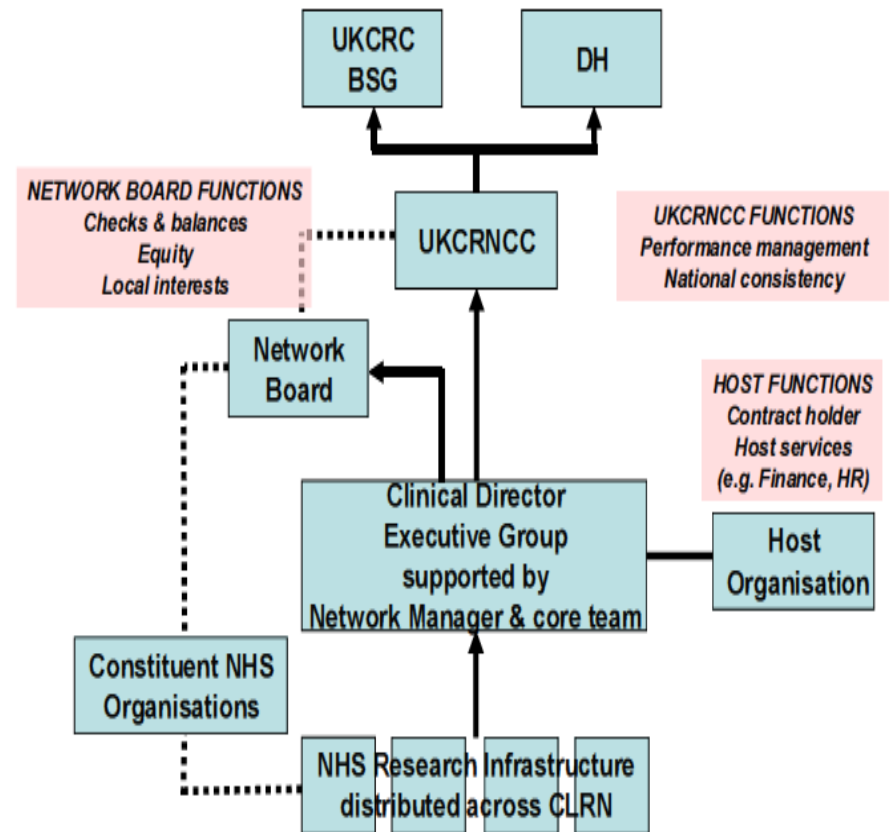
Experimental Medicine

Workforce and Training

Information Systems

Communications

CLRN Organisational Template



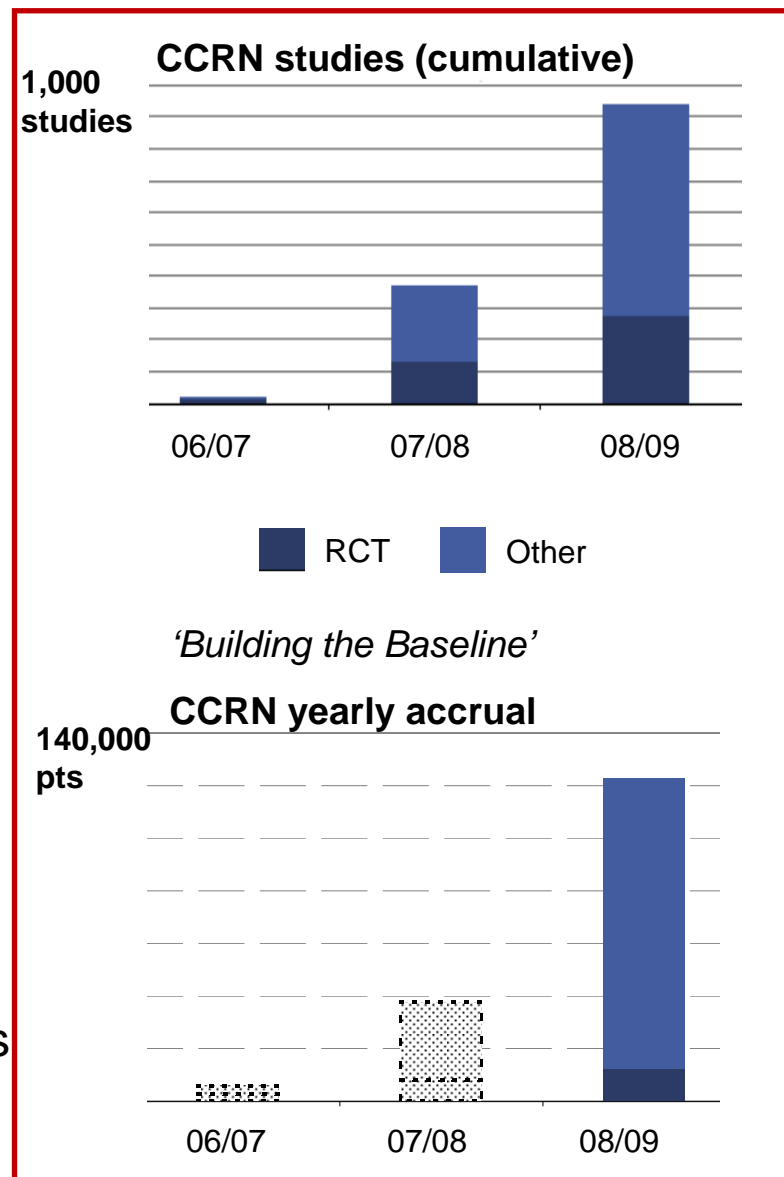
NIHR CRN and the NHS Operating Framework

'Ambition to double participation in 5 years linked to Comprehensive CRN'

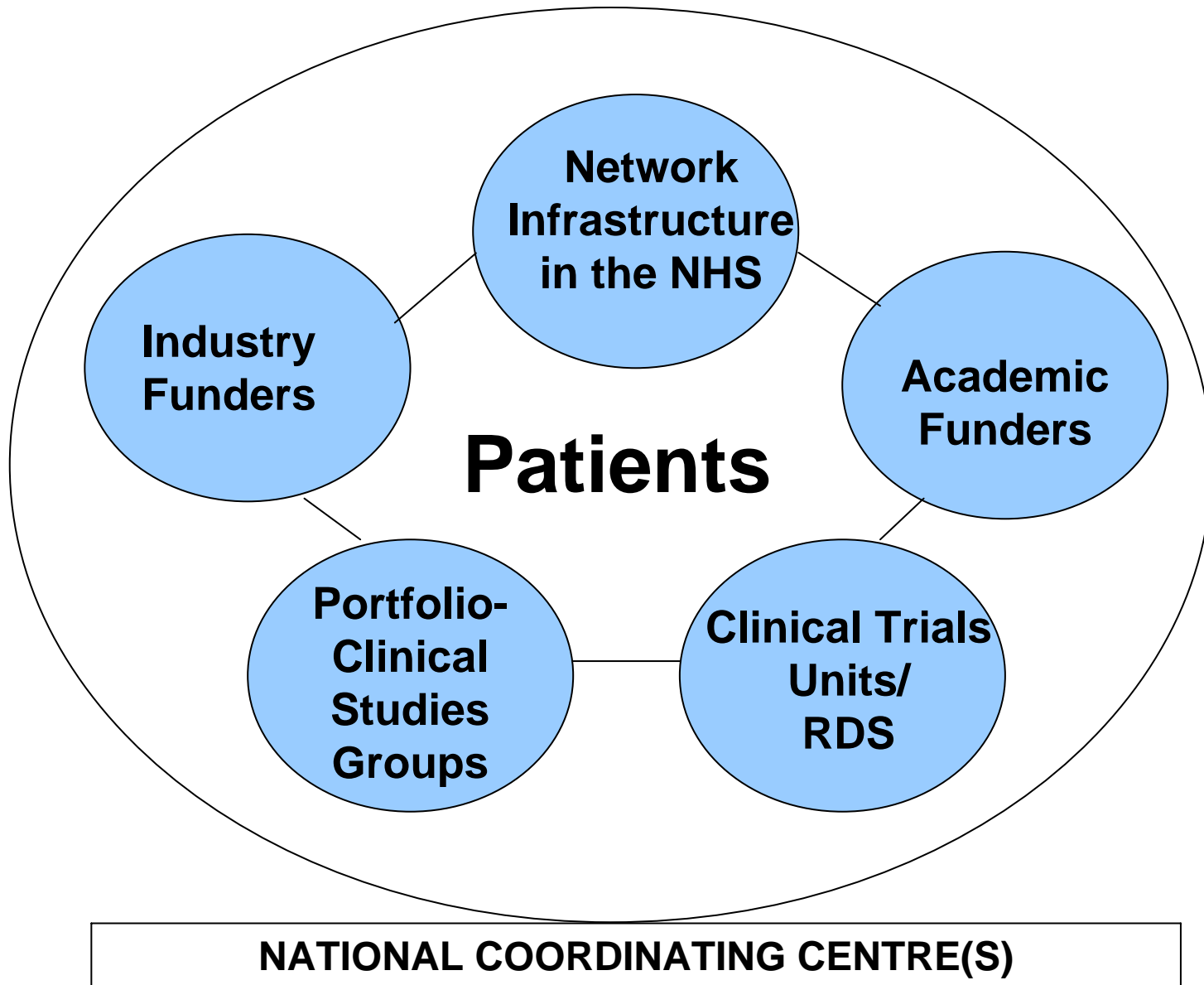
- Realism (avoid underestimating the challenge)
- Comprehensive CRN is very different from Topic CRNs
- More excellent trials (and studies)

NEED

- Actively managed approach
- Partnerships (Patients, Funders, NHS Trusts, CRNs, Government)
- Excellent and larger portfolios
- Funder engagement including portfolio development
- Adequate capacity eg Clinical Trial Units
- Coordination via CRN CC and Specialty Groups
- Adequately resourced



Benefits for Patients



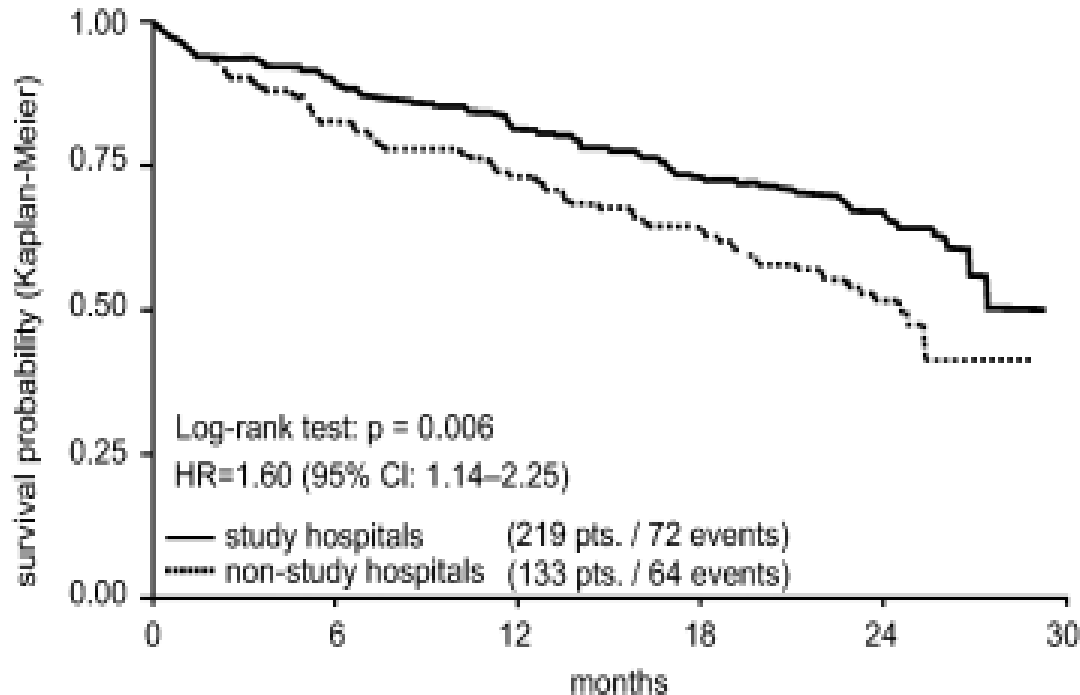
Benefits for Patients from a Research Active NHS

- **The more rapid introduction of better treatments, diagnostics, devices, and care**
- **Dissemination of excellence in clinical care**
- **Wealth as well as Health**

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Benefits for Patients



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.

1/3 of EOC in 3months in Germany in 2001 were analysed(476 pts);

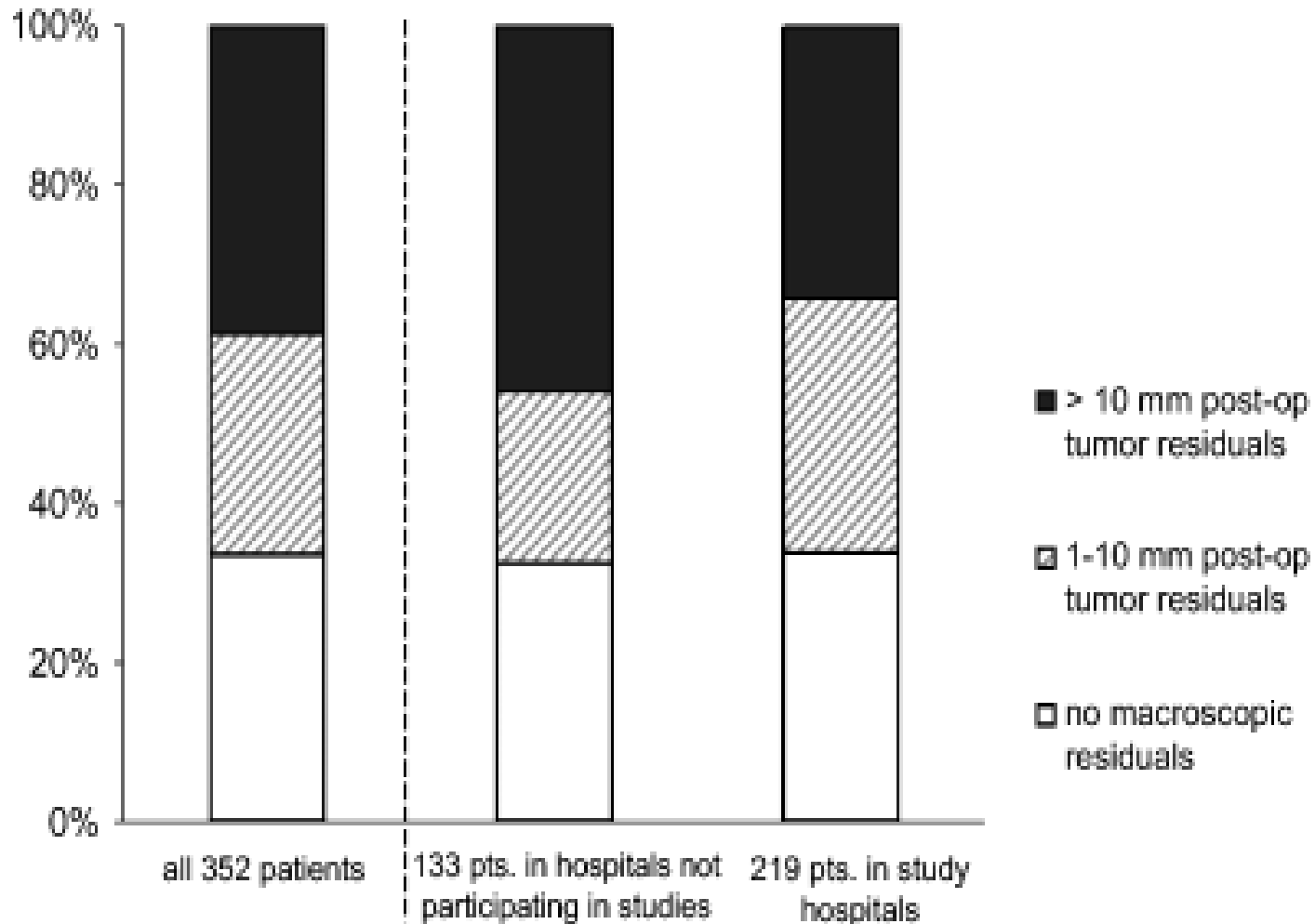
Institutions not individual patients;

80/165 hospitals participated in studies.

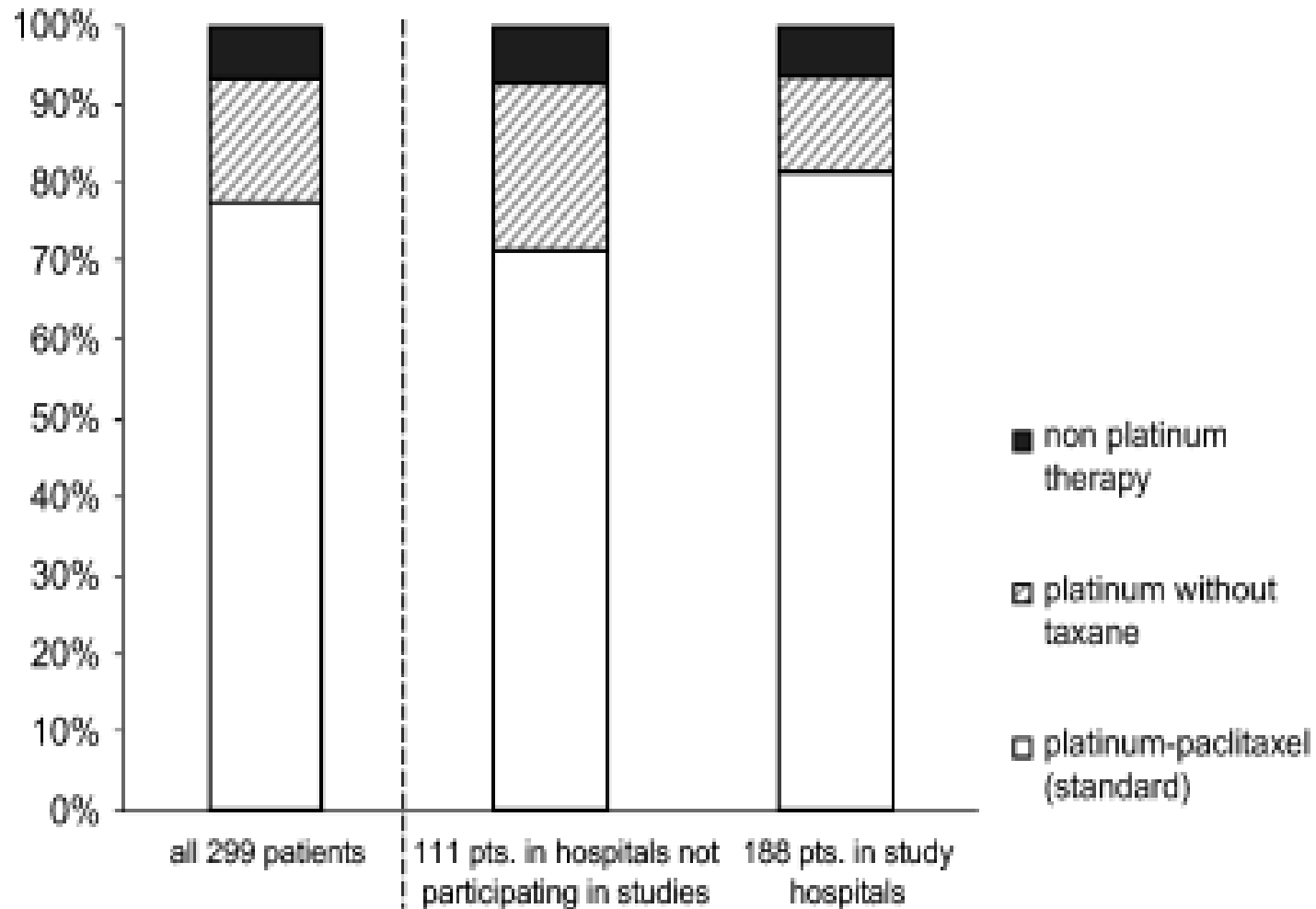
Prognostic factors for survival in invasive epithelial ovarian cancer in Germany 2001

Variable	Hazard ratio	95% Confidence interval	P value
Stage	1		
	4.01	2.11–7.62	<0.0001
PS	1		
	3.00	2.03–4.44	<0.0001
Ascites	1		
	1.91	1.35–2.71	0.0002
Institutional study participation	1		
	1.82	1.27–2.61	0.001
Comorbidity	1		
	1.77	1.23–2.54	0.002
Age	1		
	1.76	1.18–2.64	0.006
Histology, Grading and Hospital Volume were NS			

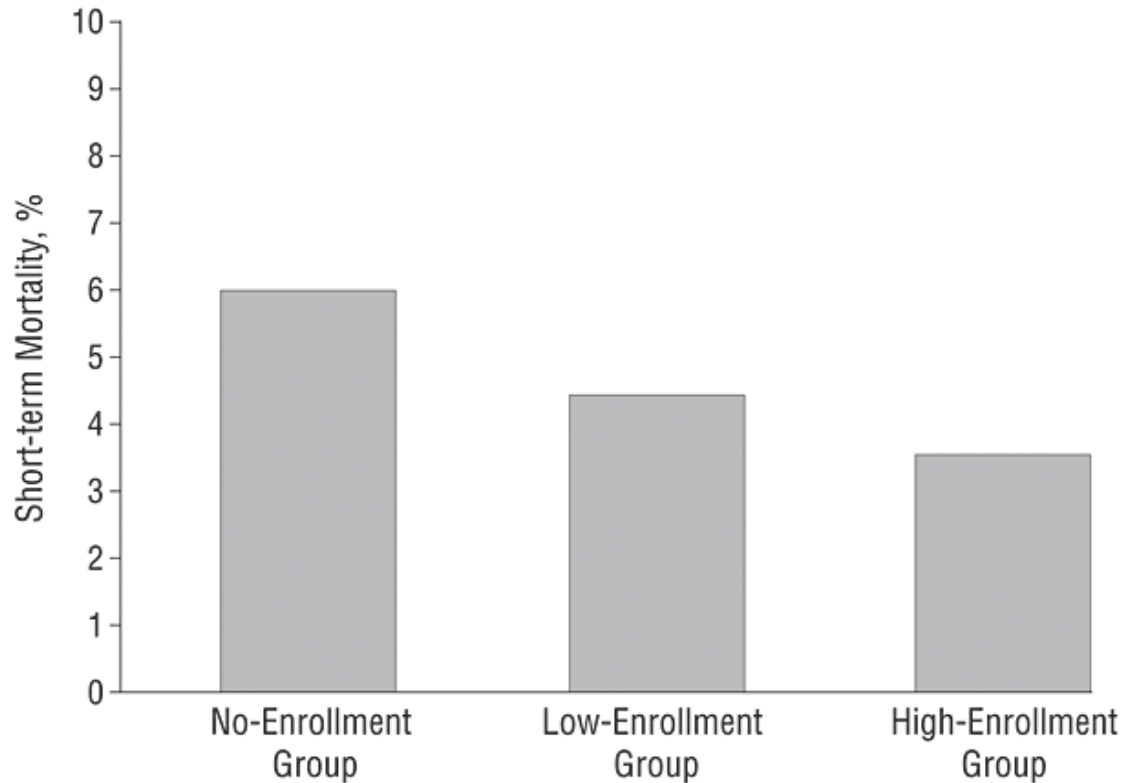
Post-operative residual tumour



Selection of Chemotherapy



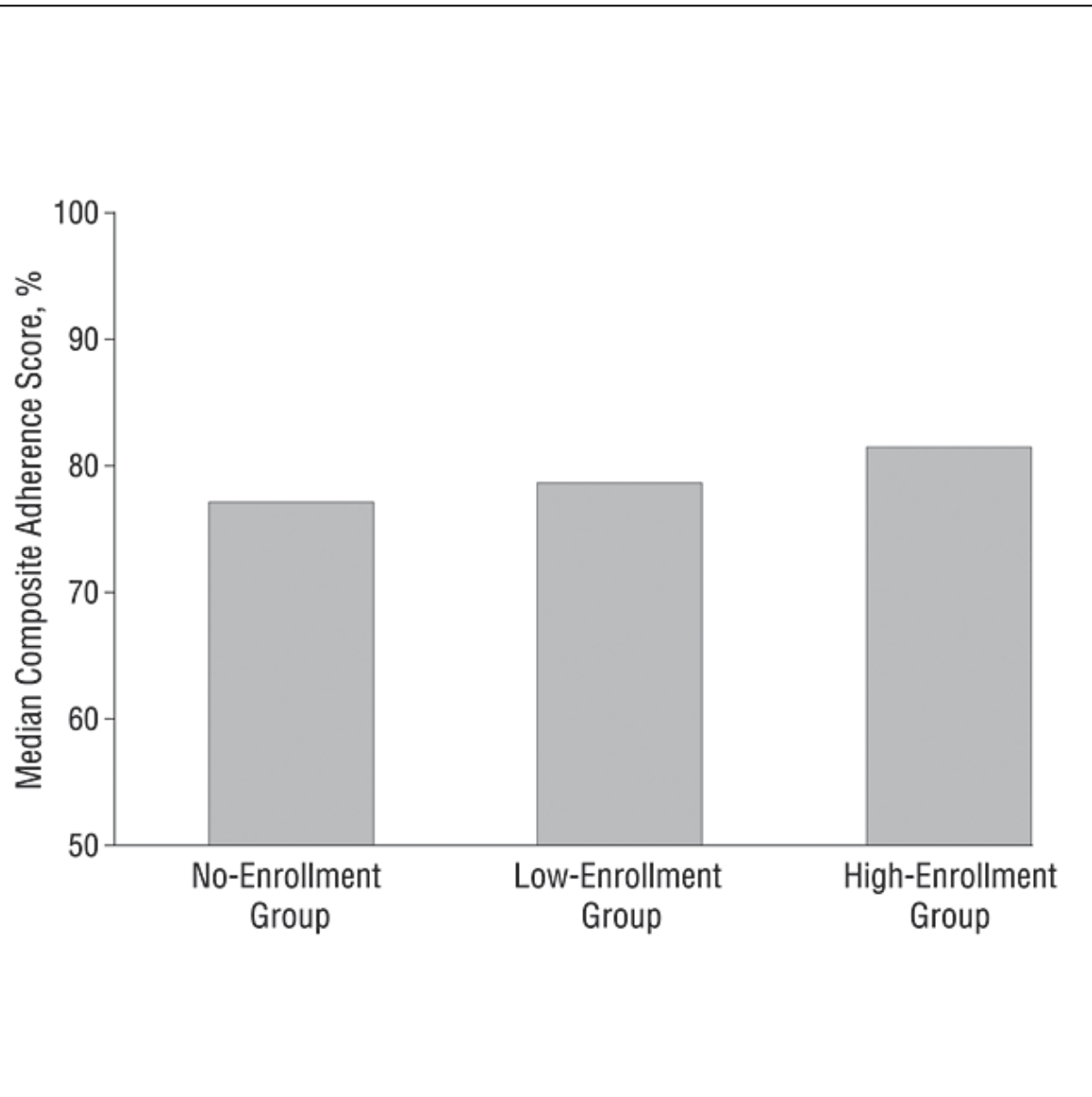
Benefits for Patients



Better outcomes for patients treated at hospitals that participate in clinical trials. Majumdar et al, Archives of Internal Medicine 2008, 168, 657.

Coronary artery disease

Benefits for Patients



Better outcomes for patients treated at hospitals that participate in clinical trials. Majumdar et al, Archives of Internal Medicine 2008, 168, 657.

Coronary artery disease

Challenges And Developments

- **Real progress**
- **Huge amount to do**
- **Pitfalls are real - bureaucracy, funding crunches, NHS, investigator and Industry engagement,**
- **Opportunity remains**