



# Costing Industry Sponsored Studies -The UKCRN Costing Template

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# Key issues affecting UK clinical research

## Time

- Long set-up times for UK trials, still significant delays with some R&D departments
- Unreliable patient recruitment

## Cost

- Delayed study set-up due to cost negotiations
- Variable trust overheads and cost transparency

## Quality

- Poor data quality due to inconsistent training of research staff
- Inadequate investigator / researcher commitment & involvement in trials

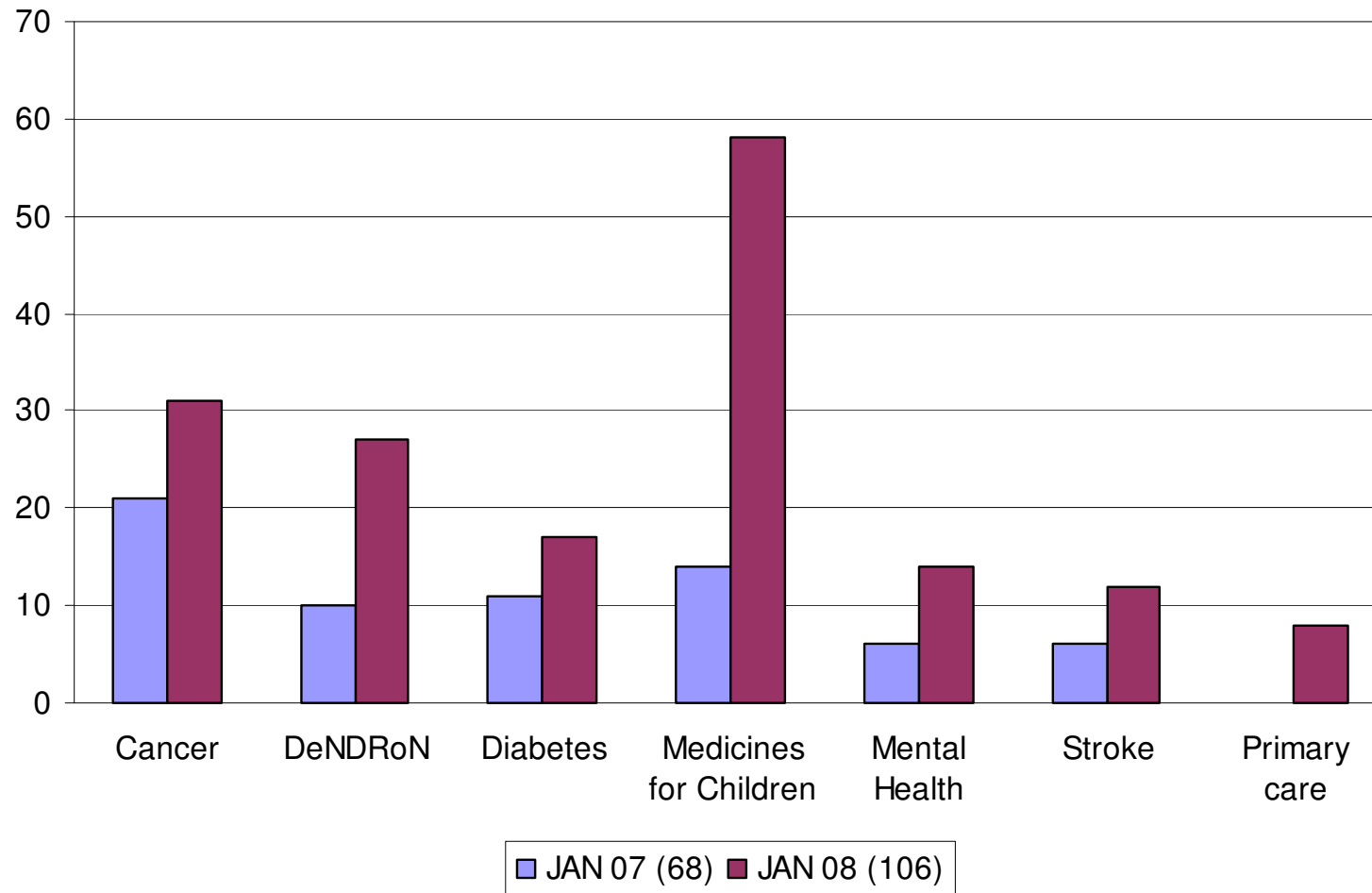


# Timelines

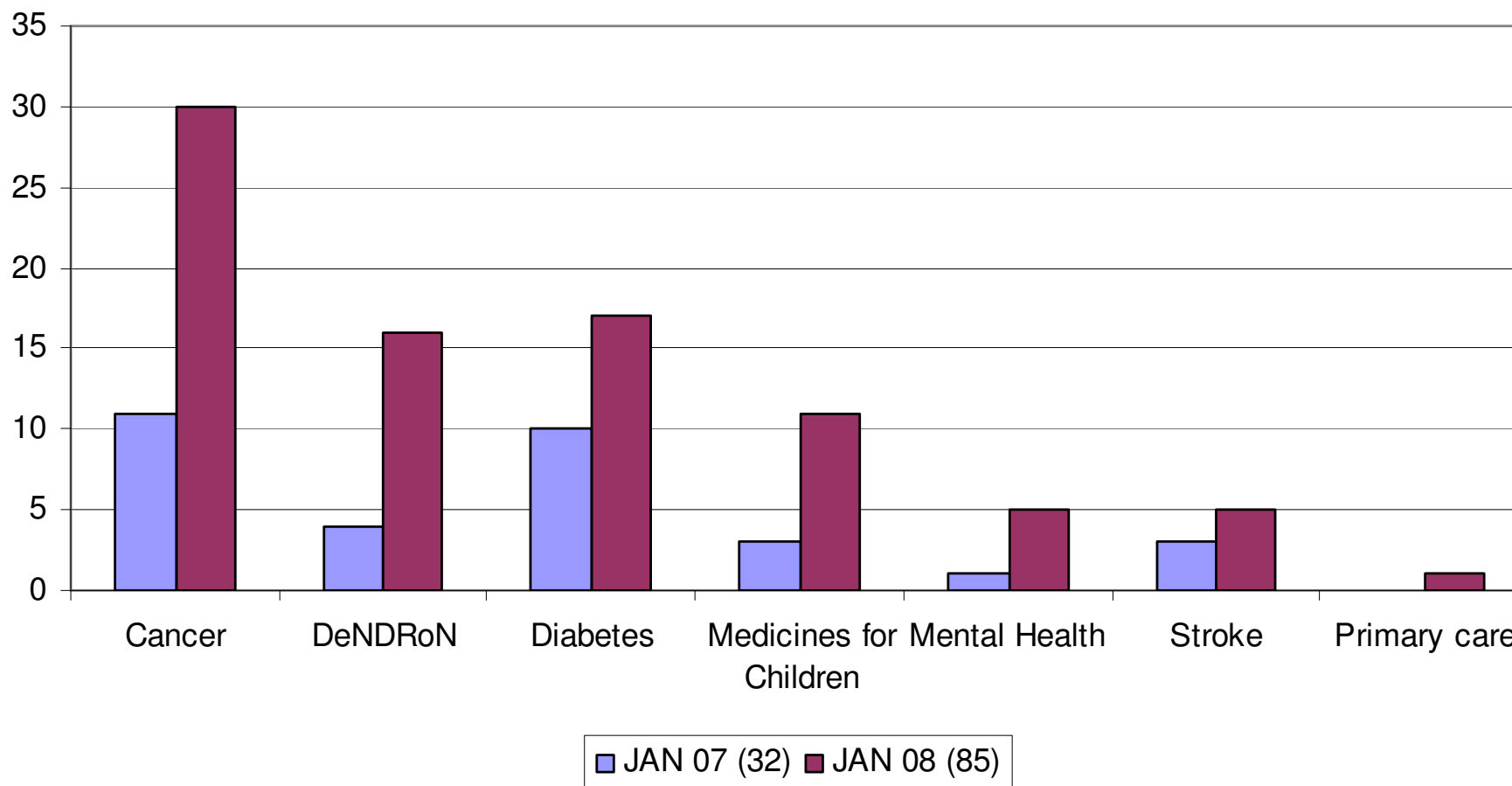


- TCRNs launched and started to adopt industry studies in 2006
- MHRN and NCRN, although established in 2003 & 2001, only accepted industry studies from 2006
- PCRN launched in April 07 and adopted first study in May
- CCRN started to consider industry studies from April 2008

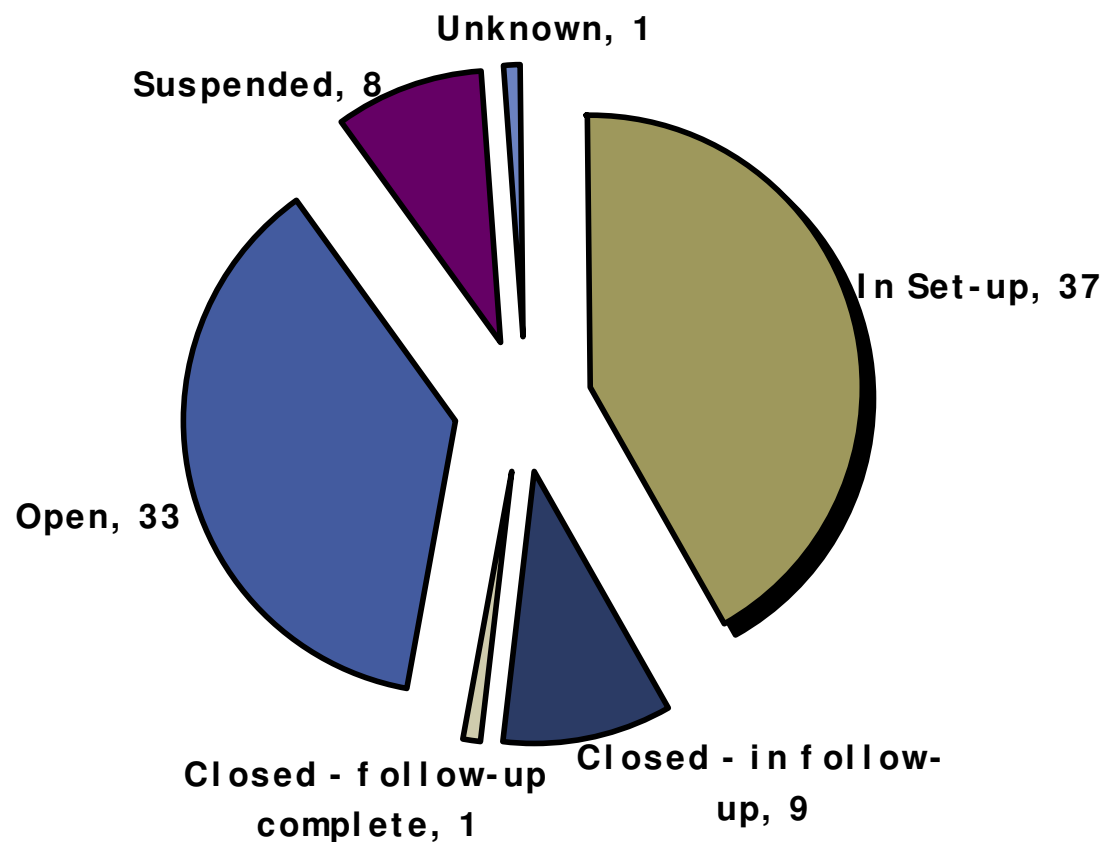
## Number of companies in liaison with Networks



## Number of studies that have been formally adopted

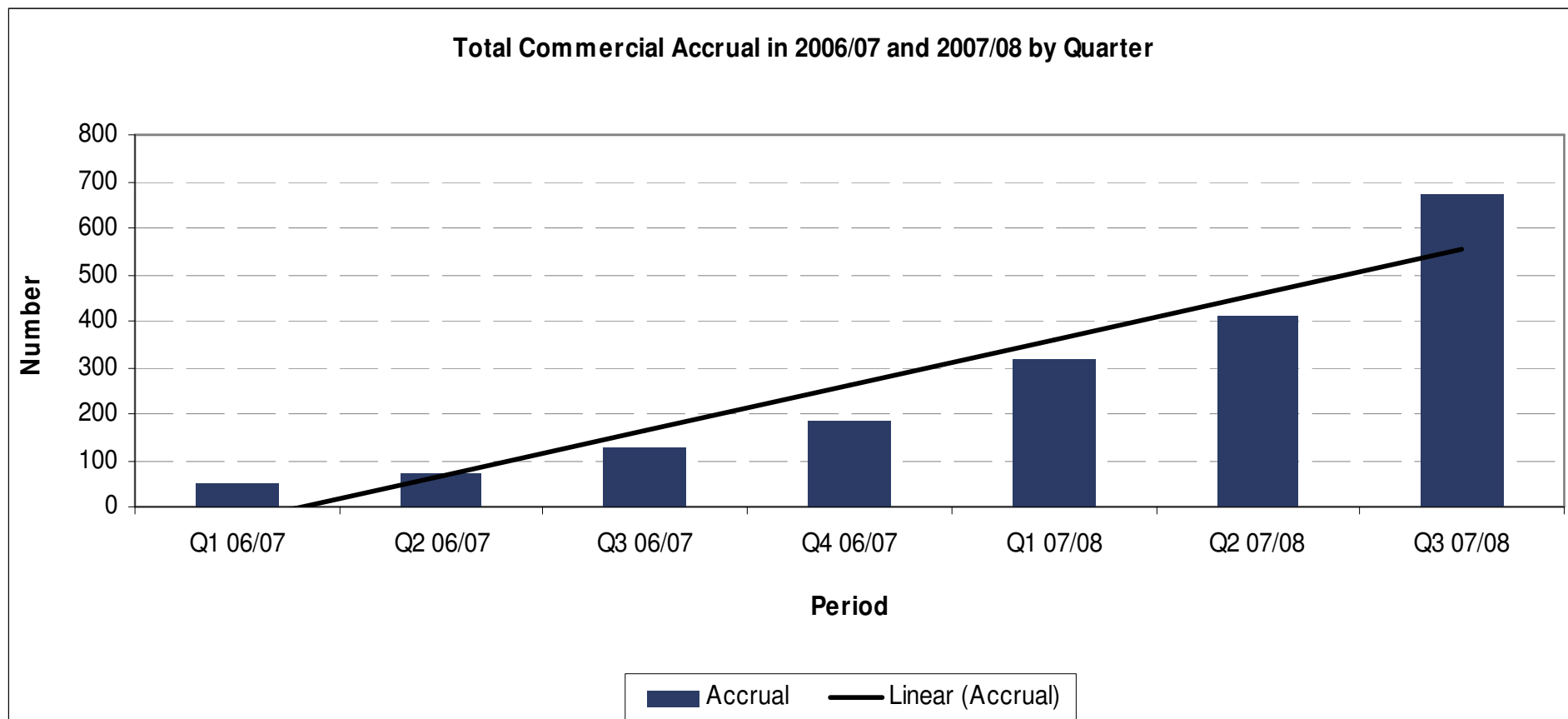


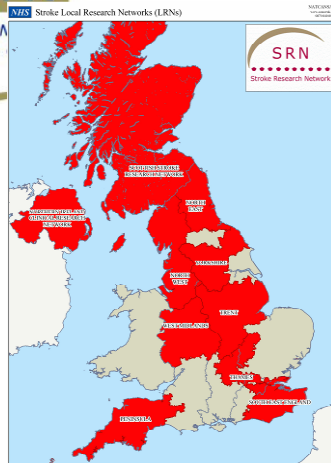
# UKCRN Industry Study Activity



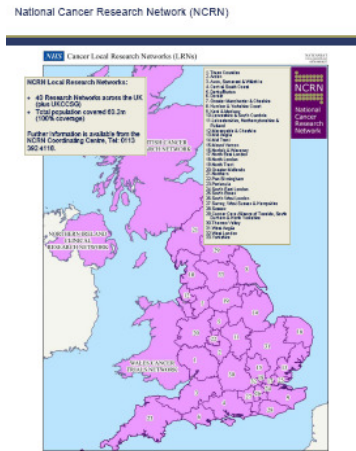


# UKCRN Industry Study Activity

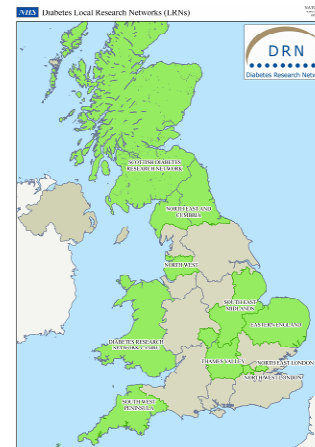




**Stroke**



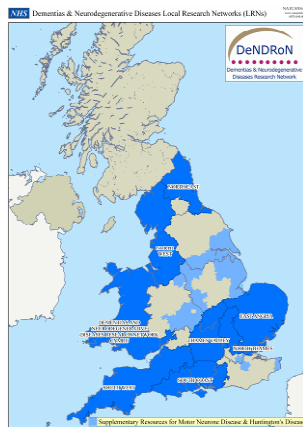
**Cancer**



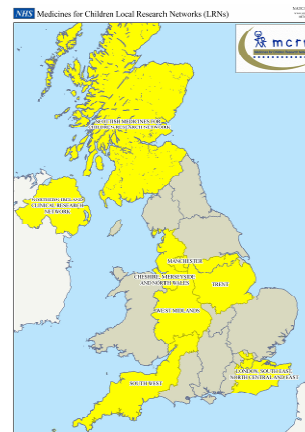
**Diabetes**



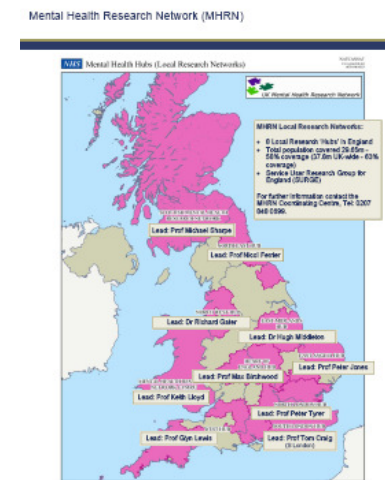
**Primary Care**



**Dementias & Neurodegenerative**



**Medicines for children**



**Mental Health**

Through 25  
Comprehensive  
Local Research  
Networks across  
England





# The UKCRN offer to Industry

## **Study delivery** to promised targets:

- Shared performance goals
- Network monitoring and performance management
- Rapid access to new sites and patient populations
- Experienced and trained research staff
- Small to large trials
- Single point of contact for network sites
- Rapid site set up through streamlined RM&G
- UKCRN 'badging' of trials

To improve the UK Clinical Research environment for Industry sponsored studies by addressing:

- **Speed**
- **Reliability**
- **Quality**
- **Value**





## Studies that require formal consideration but if accepted have a high priority

One of the aims of the NIHR CRN is to facilitate studies of benefit to patients that are sponsored by industry. A specific adoption process has therefore been developed by the UKCRC Industry Road Map Group to enable these studies to be part of the Portfolio. Studies that are accepted into the Portfolio in this way involve full cost recovery from industry.



## UKCRN Industry Services

- Consultation
- Feasibility
- Costing & contracting
- Site set-up
- Study delivery to targets



# The UKCRN Costing Project

- To develop a clear methodology to calculate consistent and transparent prices for Industry sponsored studies, to support both the NHS and Industry
- To ensure NHS Trusts are properly reimbursed for any activities associated with Industry studies
- To identify standard rates for staff time, overhead costs, capacity building, support service costs and investigations, which are acceptable to all parties
- To develop a network implemented costing process



- Develop the UKCRN Costing Template
- Benchmark the costs of clinical trials from industry
- Benchmark the costs of clinical trials from the NHS
- Develop clear guidance for networks costs
- Develop a network costing system
- Focus on secondary care in the first instance
- Launch May 2008



# Who was consulted?

- NHS R&D Forum
- NHS R&D staff
- Pharma, Biotech and Medical Device Industries
- Department of Health
- University/ academic sector
- NIHR Topic and Comprehensive Networks
- NHS Pharmacy Services

## Who led the key work streams?

- **The Costing Template** - Anne Davies, UKCRN
- **The Investigation Pricing Index** - Maria Palmer, R&D forum/ UKCRN secondee
- **The Pharmacy Working group** - Tim Root, East & South East England Specialist Pharmacy Services
- **Communications** - Clare Morgan, UKCRN

# The UKCRN Costing Template

A standard Costing Template which demonstrates:

- Staff hourly rates
- Overheads
- Capacity building

Recommended prices for

- Investigations
- Pharmacy
- NHS R&D
- Other set up costs



# Benchmarking

- Retrospective benchmarking
  - 5 companies
  - 11 studies
  - 5 potential rates for overheads and capacity building
  - Lowest, median & highest rates of PbR MFF
  - 85 iterations



# Costing Template Pilot: Real-time Benchmarking

- 12 studies
- 9 companies
- All TCRNs involved
- Six month pilot completed Jan 08

# Staff Hourly Rates

- BMA/ABPI rates have previously been widely accepted
- Develop full clarity
- Consultant hourly rate (for all medical staff):
  - £68.75 (based on 1760hours per annum)
- Nurse hourly rate:
  - £25.87 ( based at top of Agenda for Change band 7)
- Other staff – same as nurse rate
- Admin rate for specific data management (band 3)

# Overhead Costs

- Overheads include building maintenance, support services (eg general admin, finance, security, HR etc)
- Pilot overhead rate 70% **added to DIRECT costs**
- Overheads are only added once (already added to Investigations)
- Rate set following extensive benchmarking of retrospective and real time studies to ensure that overall costs were acceptable in the pilot to both NHS and Industry



<b>Staff</b>	<b>Direct Cost</b>	<b>Rate inclusive of Overheads and Capacity Building</b>	<b>Minimum Total hourly rate (with lowest PbR MFF)</b>	<b>Maximum Total hourly rate (with highest PbR MFF)</b>
<b>All Medical staff</b> (@Senior Consultant rate)	£68.75	£130.62	£130.78	£163.28
<b>Nursing staff</b>	£25.87	£49.15	£49.21	£61.43
<b>Other professional staff</b> (eg pharmacists)	£25.87	£49.15	£49.21	£61.43
<b>Admin/ data management</b>	£11.79	£22.40	£22.42	£28.00



# Capacity Building

- A capacity building rate of 20% is automatically added to basic staff costs and investigation prices
- Pilot capacity building rate 30% (will roll out with 20% as 30% slightly inflated costs)
- This surplus should be ring fenced by NHS Trusts to support local research capacity

# The Investigation Pricing Index

- Provide a standard recommended tariff for Investigations regularly used in commercial studies
- Generated from provider to provider prices for NHS services from CLRN host organisation Trusts
- The price already includes overheads but capacity building and PbR MFF is added
- Index subject to ongoing review to ensure prices are acceptable to the NHS and Industry

# Pharmacy costs

- Prices have been developed based on the time required to conduct routine research Pharmacy activities
- Pharmacy staff hourly rates (fixed at the top of *Agenda for Change* band 7) are used as the baseline for staff costs
- Study set up and closedown rates have been split into three categories with fixed prices, which reflect the complexity of the pharmacy services required
- The Template also captures other routine Pharmacy costs, eg/ dispensing prices, prescription charges
- The Pharmacy costing tool has been piloted using a number of retrospective studies, to ensure pharmacy costs are appropriate for the NHS and also for Industry.

# Addressing Variation in Costs

- Unreasonable to expect every NHS Trust to have identical costs
- There must be standardisation when addressing variation
- Addressed this variation by adopting the ***Payment by Results Market Forces Factor (PbR MFF)*** system of measuring costs for NHS service delivery, developed by the Department of Health.
- PbR MFF will be capped at 1.25 to ensure Trust competitiveness
- Discussions ongoing with appropriate factors for devolved nations

# Is this a fixed price without negotiation?

- The UKCRN cannot set a fixed price for NHS Trusts
- The UKCRN Costing Template has been developed to support rapid local costing negotiation and agreement
- Negotiations will be focused on activity rather than prices, using a transparent breakdown of all cost elements
- The participating Trust will review and feedback on the proposed prices, with clear reasons for any changes e.g:
  - Insufficient staff time allocated for a particular activity
  - A study specific activity missing from the template
  - A local requirement to conduct aspects of the study out of hours (e.g. limited availability of equipment)

# Is the UKCRN Costing Template mandatory for UKCRN Adopted studies?

- The UKCRN Costing Template is an integral part of the study adoption process
- The Template will form the basis for any discussions around study fees for UKCRN adopted Industry studies.

## Does the Network receive any of the fees?

- The UKCRN Costing Template will inform the financial arrangements documented within the mCTA
- Trusts will continue to contract directly with Companies and all fees will go directly to the Trust
- Local agreements between Trusts and Local Research Networks ensure the cost reimbursement for Network research nurse time

# The Costing Process

1. Company populate Costing Tool
2. Network CC check costs are within expected range
3. Costs presented to sites by LRNs through CLRNs
4. Negotiation of site specific costs with company, facilitated by the CLRN
5. Final costs agreed



- The UKCRN Costing Template will be closely monitored over the first 12 months and amendments will be made when required.
- If you have any concerns, suggestions or points you would like us to investigate then please email us at [costingfeedback@ukcrn.org.uk](mailto:costingfeedback@ukcrn.org.uk)



## How can I find out more?

- A full description of the UKCRN Costing Template and process, plus downloadable copies of the UKCRN Costing Template will be available on the UKCRN Website from Friday 23<sup>rd</sup> May:

[www.ukcrn.org.uk/index/industry](http://www.ukcrn.org.uk/index/industry)

### **UKCRN / CCRN Coordinating Centre**

- UKCRN Assistant Director for Industry: **Clare Morgan**
- UKCRN Associate Director for Industry: **Rick Kaplan**
- UKCRN Industry Lead: **Jenny Gray**
- UKCRN Senior fellow - Industry: **Anne Davies**
- UKCRN Senior fellow - Industry: **Sarah Crawshaw**

### **NCRN Coordinating Centre**

- NCRN Industry Lead: **Rick Kaplan**
- Principal Fellow: **Matt Cooper**

### **DRN Coordinating Centre**

- DRN Industry Lead: **Nish Chaturvedi**
- Research Coordinator: **Louise Forster**

### **MHRN Coordinating Centre**

- MHRN Industry Lead: **Tony David**
- Research Coordinator: **Jacqui Kraska**

### **Primary Care Research Network**

- Director: **Paul Wallace**
- PCRN Industry Manager: **Kate Biscomb**

### **DeNDRoN Coordinating Centre**

- DeNDRoN Industry Lead: **Ian McKeith**
- Study Delivery Manager: **Judith Headley**

### **MCRN Coordinating Centre**

- MCRN Industry Lead: **Tony Nunn**
- Industry Liaison Officer: **Andrew Rose**

### **SRN Coordinating Centre**

- SRN Industry Lead: **Philip Bath**
- Portfolio Manager: **Dave Smith**



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