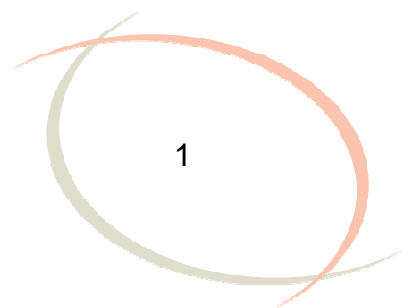
A large, decorative graphic consisting of two overlapping swooshes. The outer one is olive green and the inner one is red, both curving around the central text.

**Costing Industry  
sponsored studies through  
the NIHR Networks  
(Pharma/biotech contract  
research in secondary care)**



<b>1</b>	<b>SUMMARY</b> .....	<b>3</b>
<b>2</b>	<b>BACKGROUND -THE CHALLENGES OF DEVELOPING A ROBUST SYSTEM</b>	<b>3</b>
<b>3</b>	<b>HOW HAS THE NIHR CRN INDUSTRY COSTING PROCESS BEEN DEVELOPED?</b> .....	<b>4</b>
<b>4</b>	<b>WHAT DOES THE NEW INDUSTRY COSTING PROCESS CONSIST OF?</b> .....	<b>4</b>
<b>5</b>	<b>HOW DOES THE INDUSTRY COSTING PROCESS ADDRESS THE VARIATION OF COSTS FOR NHS TRUSTS?</b> .....	<b>5</b>
<b>6</b>	<b>HOW WILL COMPANIES USE THE NEW NIHR CRN INDUSTRY COSTING PROCESS?</b> .....	<b>5</b>
	<b>6.1 Negotiations</b> .....	<b>6</b>
<b>7</b>	<b>ONGOING REVIEW AND CONTACTS</b> .....	<b>6</b>
	<b>ANNEX 1 EXTRACT FROM THE NHS FINANCE MANUAL</b> .....	<b>8</b>
	<b>ANNEX 2 KEY ELEMENTS OF THE INDUSTRY COSTING TEMPLATE</b> .....	<b>10</b>
	<b>1. Per Patient Budget</b> .....	<b>10</b>
	1.1. Trials Staff rates .....	<b>10</b>
	1.2. Overhead rates .....	<b>10</b>
	1.3. Capacity building .....	<b>11</b>
	1.4. Summary .....	<b>11</b>
	1.5. Regular uplifts.....	<b>11</b>
	<b>2. What is the Investigation Pricing Index and how has it been developed?</b> .....	<b>11</b>
	<b>3. How are pharmacy costs calculated?</b> .....	<b>12</b>
	<b>4. NHS R&amp;D Costs</b> .....	<b>12</b>
	<b>5. Other Costs</b> .....	<b>12</b>
	<b>5.1 Subsistence Costs</b> .....	<b>12</b>
	<b>5.2 Travel Costs</b> .....	<b>12</b>
	<b>5.3 Archiving costs</b> .....	<b>12</b>
	<b>5.4 4 Monitoring visits</b> .....	<b>13</b>
	<b>6. The Timecard</b> .....	<b>13</b>
	<b>ANNEX 3 HOW DOES THE NIHR CRN INDUSTRY COSTING PROCESS ADDRESS THE VARIATION OF COSTS FOR NHS TRUSTS?</b> .....	<b>14</b>
	<b>ANNEX 4 THE NIHR CRN INDUSTRY COSTING GROUP MEMBERSHIP:</b> .....	<b>15</b>
	<b>ANNEX 5 GLOSSARY</b> .....	<b>16</b>

# Costing Industry Sponsored Studies Through the National Institute for Health Research Networks

## 1 SUMMARY

The Industry Costing Template has been developed to speed up the initiation of industry contract trials by reducing the time required for site-by-site negotiations. It is based on the principles articulated in the NHS Finance Manual and is intended to provide transparency, greater consistency and predictability on costings for companies.

This version has been developed for use in contract trials of pharmaceutical and biotechnology agents in secondary care. Templates suitable for use in primary care studies and in studies of medical devices are being developed.

It will be used for all relevant studies intended for adoption by the National Institute for Health Research (NIHR) Clinical Research Networks (England). Although developed primarily to support these studies, the methodology is freely available to companies interested in running trials outside the Networks. NIHR CRN is working with the devolved nations to facilitate development of comparable systems for implementation across the UK.

The Template has been developed and piloted in a collaborative process involving the NHS and industry stakeholders. It will be reviewed and updated, as required, in the light of broader experience.

## 2 BACKGROUND -The challenges of developing a robust system

### Introduction

Over the last eighteen months, the NIHR CRN has been leading on a Costing Project to develop a clear and transparent process which will provide industry and the NHS with a consistent method of costing industry contract research carried out within the NIHR Networks. Attention has focussed on contract trials of pharmaceutical and biotechnology products conducted in secondary care, which is the focus of this document. Templates suitable for use in primary care and in studies of medical devices are under development.

This work has been developed on behalf of the NIHR and addresses a specific recommendation made in the Cooksey Report, which highlighted the need for a transparent and consistent national costing system. Although developed primarily for the facilitation of studies managed via the NIHR Networks, the methodology is also freely available to companies intending to run trials outside of the Networks

The UK tends to be more expensive than the rest of Europe for conducting industry-sponsored studies and this can be partially attributed to the recognised higher cost of living. However, this does not account for the widely varying cost of conducting a study throughout the UK and the inconsistent and non-transparent methods used to calculate commercial prices. In some cases, NHS Trusts may not be properly reimbursed for the services provided to Industry whereas other NHS Trusts demand unrealistically high fees. This variability in prices, especially for multi-centre studies, linked with unreliable delivery of patients and their data, is identified by industry as a significant factor in explaining why the UK is not seen by some as a cost-effective place to conduct later phase clinical trials.

The new NIHR CRN Industry Costing process will:

- Provide a clear methodology to calculate consistent and transparent prices associated with industry-sponsored studies to support both industry and the NIHR Networks
- Ensure all NHS Trusts are fully reimbursed for any activities associated with industry studies, in accordance with the requirements of the NHS Finance Manual (Annex 1)
- Identify standard rates for staff time, overheads, capacity building, investigations and costs for departments supporting research, which are acceptable to all parties
- Speed up the negotiation process for costing and is one of several tools being introduced to speed up trial initiation and ensure the Networks provide a value for money environment for trials
- Provide clear guidance for Industry and the public sector
- Be implemented through the NIHR Networks for all relevant studies

### **3 How has the NIHR CRN Industry Costing process been developed?**

NIHR CRN has worked closely with key stakeholders to ensure that the new NIHR CRN Industry Costing process is robust and effective. The NIHR CRN Industry Costing Project was developed with the advice and support of three key groups. The UKCRC Industry Road Map Group, the NIHR CRN Industry Costing Group and the NIHR CRN Pharmacy Sub Group. The UKCRC Industry Road Map Group steers the development of the overall NIHR CRN agenda for commercial research, whereas the NIHR CRN Industry Costing Group was formed specifically to provide expertise to assist NIHR CRN in the development of the costing process for industry-sponsored studies. The Pharmacy Sub Group has provided significant input in designing the pharmacy costing tool and assisting with benchmarking pharmacy costs.

A NIHR CRN Industry Costing Group was formed which included representatives of the pharmaceutical industry, Contract Research Organisations, NHS R&D Forum, NHS R&D staff, Department of Health, University/ academic sector, NIHR Topic and Comprehensive Clinical Research Networks and NHS Pharmacy Services. Members provided expert advice on the development of the Industry Costing Template, the Investigation Pricing Index, pharmacy costing and appropriate communication needs.

The NIHR CRN Industry Costing project has focussed primarily on pharmaceutical studies in NHS Hospital Trusts and the Industry Costing Template has been designed for use with studies in a secondary care setting. Primary Care specific arrangements are also being developed and guidance will be published in due course. A template for costing medical device contract studies is also in development (through the NIHR Medical Devices Clinical Research Working Group). Please contact the Industry Team at NIHR CRN Coordinating Centre for further information about costing these types of studies.

### **4 What does the new NIHR CRN Industry Costing process consist of?**

At the heart of the new costing process is the Industry Costing Template, which has been developed to provide a standard tool to calculate the prices associated with

individual industry-sponsored studies conducted through the NIHR Clinical Research Networks. This Excel tool is available on the NIHR CRN website and includes separate sections covering:

- Instructions for completion
- Per Patient Budget
- Investigation Pricing Index
- Pharmacy Budget
- NHS R&D Budget
- Other Costs
- Payment by Results Market Forces Factor (PbR MFF)
- The Timecard

The Industry Costing Template provides an easy to use method of calculating the contract price of an individual industry-sponsored study. The activities documented in the protocol are entered by the company and the template automatically calculates the full costs of the study at the site (i.e. the cost to the NHS inclusive of direct costs and overheads) and the total price to be charged to the company (which comprises the full cost plus a, capacity building element and a local cost adjustment for each Trust, via PbR MFF). The Industry Costing Template captures the staff time required, investigations and their frequency and set up charges. It is designed to ensure that the costs of all activities undertaken at the site are included in the final price charged to the sponsor.

Details of key elements of the template are provided in Annex 2.

## 5 How does the NIHR CRN Industry Costing process address the variation of costs for NHS Trusts?

The Industry Costing Template standardises the rates for staff, investigations and support services and recognises that the cost of providing facilities to conduct clinical research varies between NHS Trusts. The NIHR CRN have 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. Further details are provided in Annex 3.

## 6 How will companies and CROs use the new NIHR CRN Industry Costing process?

The process for completion and submission of the Industry Costing Template is detailed below. Further advice can be obtained through the NIHR CRN helpline [crncc.costinghelp@nihr.ac.uk](mailto:crncc.costinghelp@nihr.ac.uk) or through the NIHR CRN Industry team Tel: 0113 343 0341

1. Companies should download a copy of the Industry Costing Template and guidance documents from the NIHR CRN Website: [www.crncc.nihr.ac.uk/index/industry.html](http://www.crncc.nihr.ac.uk/index/industry.html)
2. The company will populate the Industry Costing Template and send it electronically to the appropriate Coordinating Centre (either TCRN or NIHR CRN) with supporting documentation for Adoption (i.e. the NIHR CRN Submission form (which can be found at [www.crncc.nihr.ac.uk/index/industry.html](http://www.crncc.nihr.ac.uk/index/industry.html)), the protocol, the study visit outline).

3. The Coordinating Centre will review the proposed costings with a relevant expert trialist to ensure the NIHR CRN Industry Costing Template has been completed appropriately and is within the expected price range for the complexity of the study. The Industry Costing Template will then be sent with a summary, anonymised with respect to the company and IMP details (within the NIHR CRN Submission form) to the Local Research Networks, to support identification of potential Investigators and gain Expressions of Interest.
4. Once the study is adopted and the site is confirmed by the Company, the Local Research Networks will provide their sites/Trusts with the Industry Costing Template, obtain any feedback or requests for amendments to the proposed costing and provide clear reasons for any changes.  
Reasons for amendments might include:
  - 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)
5. Responses to the proposed costing will be fed back to the company via the Coordinating Centre.

## 6.1 Negotiations

This method of costing ensures that all required activities are clearly documented and the associated time captured. The completed Industry Costing Template will form a clear basis for any negotiation facilitated by the Local Research Networks, as NIHR CRN cannot set a fixed price for research activities within the NHS. It is anticipated that there will be little scope for local negotiation if all time and requirements have been captured appropriately within the final price. However, there may occasionally be specific local issues that need to be considered by the company. The timing of activities or specific issues with regard to the delivery of investigations should form the basis of negotiations and not the Per Patient budget (although this will need to be considered). Site staff will be able to comment on the time allocated to specific activities and through this, influence the final per patient budget.

It is anticipated that this method of costing will significantly reduce the time taken to negotiate cost and contracts with sites and this will be facilitated through the Local Research Networks (primarily of the NIHR CCRN).

The NIHR Comprehensive Local Research Networks (CLRNs) will ultimately coordinate the local negotiation process on behalf of the TCRNs, PCRNs and CCRNs once they are fully implemented. However during roll out, NIHR CRN will work with all Networks at both Coordinating Centre and Local Research Network level to ensure a smooth review and negotiation process is conducted on behalf of the company.

## 7 Ongoing review and contacts

The Costing Template has been piloted and the NIHR CRN Costings Group and UKCRC Industry Road Map Group consider it ready for launch. The methodology, rates, Investigation Pricing Index and NIHR CRN Industry Costing Template format described in this paper will be monitored and reviewed periodically by NIHR CRN. Adjustments may be made if an aspect of the costing process is found to be unfit for purpose and feedback on any issues or proposed changes should be sent to:

[crncc.costingfeedback@nihr.ac.uk](mailto:crncc.costingfeedback@nihr.ac.uk)

For general help and advice about any aspect of using the Industry Costing Template please contact:

[crncc.costinghelp@nihr.ac.uk](mailto:crncc.costinghelp@nihr.ac.uk)

NIHR CRN Industry Team Tel: 0113 343 0341

Updates to the Industry Costing Template will be made on a regular basis, therefore users should always download a new version of the Industry Costing Template from the NIHR CRN website for each study:

<http://www.crncc.nihr.ac.uk/index/industry.html>

## ANNEX 1 Extract from the NHS Finance Manual

### Research and Development (R&D)

- 30.47 The Prime Minister's Pharmaceutical Industry Competitiveness Task Force (PICTF, March 2001) reported an inconsistent approach to costing for commercial R&D activity in the NHS. The Department agreed to clarify guidance to promote a more consistent and transparent approach to pricing.
- 30.48 The current policy for commercial R&D in the NHS is in two guidance documents:
- HSG (97) 32 Responsibilities for meeting patient care costs associated with research and development in the NHS),  
[http://www.dh.gov.uk/PublicationsAndStatistics/LettersAndCirculars/HealthServiceGuidelines/HealthServiceGuidelinesArticle/fs/en?CONTENT\\_ID=4018353&chk=ZUXc1q](http://www.dh.gov.uk/PublicationsAndStatistics/LettersAndCirculars/HealthServiceGuidelines/HealthServiceGuidelinesArticle/fs/en?CONTENT_ID=4018353&chk=ZUXc1q) and
  - Commercial sponsorship: ethical standards for the NHS, November 2000)  
[http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT\\_ID=4005135&chk=2dVITD](http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4005135&chk=2dVITD)
- 30.49 This section supplements that guidance and should be read in conjunction with it. All NHS income derived from commercial R&D activity is raised through Income Generation powers. NHS bodies engaged in this activity should make arrangements to ensure they comply fully with this guidance, including the accounting requirements. The guidance requires income generation activity to be profit making but does not specify target levels.
- 30.50 The Department has assured the pharmaceutical industry that it wishes to support and encourage R&D in the NHS. The creation of UK Clinical Research Collaboration in 2004 is one of the measures introduced to facilitate this. The NHS should not subsidise commercial R&D. That would divert resources from patient care. On the other hand, the Government does not wish the NHS to take advantage of market conditions to maximize profits, because of the wider benefits of conducting R&D activity to NHS patients in this country.
- 30.51 Paragraph 30.20 states that where an item or service is considered an integral part of a patient's treatment (treatment in this context includes diagnostic procedures) then a charge should not be made. Income generation powers must not be used to carry out the delivery of core functions. Therefore, when costing out commercial studies, NHS bodies may not seek to recover from industry the costs of standard treatment that would otherwise have been incurred in treating patients in the NHS. NHS bodies' costing may include only activities, tests, treatments, etc which are in addition to normal treatment of the condition concerned. The exception is that, in accordance with the normal conventions for commercial clinical trials, the company sponsoring the trial is expected to supply free the medicine that is the subject of the trial.
- 30.52 In discussions on pricing with companies proposing to undertake commercial studies, NHS bodies should seek to disaggregate costs, with appropriate overheads related to each separately identified item, to avoid the use of

general overheads. This approach is in line with Government policy to improve transparent pricing in selling government services into wider markets. Guidance is provided in the document “Guidance to Facilitate the Conduct of Commercially Funded Research in the National Health Service (Secondary Care)”, January 2005, produced by the NHS Research and Development Forum, ABPI and the Institute of Clinical Research ([www.rdforum.nhs.uk](http://www.rdforum.nhs.uk)).

30.53 NHS bodies should consider in the context of all their functions how they propose to utilise funds generated through commercial R&D activity. It is acceptable to plan for profit to be used within the NHS body’s own managed R&D programme, but this is a matter for agreement with the NHS body’s Board and Chief Executive.

30.54 Guidance on contract research and on collaborative or co-funded research related activity is given in the Clinical Research Report of the Pharmaceutical Industry Competitive Task Force which was published in March 2002 ([www.advisorybodies.doh.gov.uk/pictf](http://www.advisorybodies.doh.gov.uk/pictf)).

## ANNEX 2 Key elements of the Industry Costing Template

### 1. Per Patient Budget

One of the key objectives of the NIHR CRN Industry Costing Project was to establish clarity about the method of calculation of the prices charged to Industry by the NHS, for industry-sponsored studies. The Per Patient Budget page in the Industry Costing Template enables automatic calculation of a per patient price for individual clinical trials. Following wide consultation, extensive benchmarking and piloting, hourly rates for staff costs, overheads and capacity building have been established and are fixed within the template. During the first year, the implementation of the Industry Costing Template will be closely monitored and fixed rates will be changed if they prove to be either too high or too low.

#### 1.1. Trials Staff rates

Historically, the APBI/BMA staff rates were widely accepted and used by both Industry and the NHS; these rates incorporated all costs including overheads. Unfortunately, as there was no clear breakdown of these rates some NHS Trusts would add an additional overhead charge on top, resulting in overly inflated prices. The new Industry Costing Template provides a full breakdown of all costs and is based on real NHS costs. It clearly demonstrates the direct NHS costs for each activity based upon staff category, to which overheads and capacity building are then added, resulting in a final staff price. During the Industry Costing Template Pilot, this transparent system of calculating costs was compared with studies costed using traditional methods with the ABPI/ BMA rates and clearly demonstrated that the Industry Costing Template did not inflate prices and ensured full cost recovery to the NHS.

**Clinical time** - The clinical hourly rate has been calculated at **£74.23** which is the direct cost of employing a senior consultant (i.e. 2009-10 hourly rate of pay plus employers contributions). This rate will be used in the Industry Costing Template for **ALL** medical staff irrespective of grade.

**Nurse time & other professional staff (e.g. pharmacists)** -The NIHR CRN hourly staff rate has been agreed at the top of *Agenda for Change* band 7 at **£29.28**. **Admin time** – The NIHR CRN hourly admin rate is set at the top of *Agenda for Change* band 3 at **£13.53**. The admin rate will only be used for studies which require specific data entry or other discrete/defined tasks, by an admin assistant. It is not to be used for calculating general admin duties such as clinician's secretarial costs which are included in the overhead rates described below.

#### 1.2. Overhead rates

The term 'overhead' has been specifically used within this project as it is the most commonly used term by both the NHS and industry. It refers to the essential indirect running costs incurred by an organisation, conducting research and has an impact on all aspects of the organisation's business including heating, lighting, building maintenance, security, finance, general admin, human resources, corporate management and all other resources which allow the organisation to function.

It is important that each NHS organisation charges an overhead rate to cover the cost of the infrastructure (indirect costs), which allows clinical trial activity to take place. **The overhead rate is fixed in the Industry Costing Template and it is important to recognise that overheads are only added to direct staff costs.**

Following consultation and extensive benchmarking, using both retrospective and real time studies to ensure that overall costs were acceptable to both NHS and industry, the overhead rate has been set at **70%**.

The Industry Costing Template will ensure that NHS organisations are properly reimbursed for their direct and indirect costs and that **overheads are only added once**.

### 1.3. Capacity building

It has been agreed through consultation with key stakeholders, that a capacity building margin should be incorporated into the final price. This rate has been set at **20%** and is also added to **direct staff** and **Investigation costs**. The income raised through this element should be ring fenced within NHS Trusts to build research capacity and should not be used for any other purpose.

### 1.4. Summary

The staff, overhead and capacity building rates have been developed through a rigorous benchmarking process and with the support, advice and guidance of the members of the NIHR CRN Industry Costing Group and the UKCRC Industry Roadmap Group. Benchmarking and a six month pilot of adopted TCRN Industry studies has ensured that final negotiated prices have not been inflated for Industry and that the NHS is fully reimbursed for services provided.

Direct staff costs (e.g. clinician hourly rate = £74.23), will have 70% overheads and 20% capacity building added. Therefore one hour of clinical time calculated using the Industry Costing Template will cost £141.04. As all costs also have a Payment by Results Market Forces uplift, as described previously, the maximum clinician hourly rate becomes £176.30 per hour when multiplied by the maximum PbR of 1.25.

### 1.5. Regular uplifts

Staff rates will be increased in accordance with NHS salaries at the beginning of each financial year but only those studies which are expected to run for more than two years will be subject to new staff rates after this period.

## 2. What is the Investigation Pricing Index and how has it been developed?

An important element of the NIHR CRN Industry Costing process is the Investigation Pricing Index which has been developed to capture the research investigations commonly used in Industry studies. More than twenty-five *Provider to Provider* data-sets from NHS organisations were collected through the NIHR Comprehensive Local Research Networks; these data contain the prices that the NHS host organisation charges another NHS organisation for a specific investigation. Any outlying data points were removed by subtracting any prices greater than one standard deviation from the mean and the PbR MFF was removed from each individual Trust price. These data were then used to establish a mean cost for each investigation. The prices will have **20%** capacity building added by the Industry Costing Template but overheads will **NOT** be added as they have already been included by Trusts. The PbR MFF multiplier will also be used for Investigations.

### 3. How are pharmacy costs calculated?

The method of calculating pharmacy costs, within the Industry Costing Template, has been developed for NIHR CRN by a pharmacy working group led by Tim Root, East & South East England Specialist Pharmacy Services. This work has had considerable support from the Institute of Clinical Research Pharmacy Special Interest Group, clinical trials pharmacists throughout the NHS and a number of key UK chief pharmacists to provide strategic oversight. A breakdown of Pharmacy activities has been identified and average recommended times have been allocated for each. Set up activities have been categorised into three bands, which are complexity-based and range from a simple dispensing study to a complex study involving aseptic technique. Timing required for individual activities within these bands has been agreed within the working group, leading to three fixed prices for set up. The staff rate is, as described earlier, set at the top of *Agenda for Change* band 7.

The Pharmacy costing tool, within the Industry Costing Template has been piloted within the NHS using a number of retrospective studies, in order to ensure pharmacy costs are appropriate for the NHS and also for Industry.

### 4. NHS R&D Costs

The implementation of the NIHR Comprehensive Clinical Research Network (CCRN) will have a major impact on NHS R&D management for NIHR CRN portfolio studies, although each individual NHS Trust will still be required to conduct local checks, issue approval and sign the mCTA.

An NHS R&D set up fee will be captured in the Industry Costing Template to reimburse local R&D activities.

### 5. Other Costs

Additional legitimate study costs will also be captured in the Industry Costing Template. This might include set up costs for a department providing services for a trial

#### 5.1 Subsistence Costs

Patients who are required to remain at the site for three hours or more should be offered appropriate refreshments or a meal. These costs should be entered into the Industry Costing Template.

#### 5.2 Travel Costs

It is often difficult to estimate the reimbursement costs for patient travel at the beginning of a study. A maximum amount per patient per visit should be established with the company.

#### 5.3 Archiving costs

It is important to establish archiving arrangements at study set up. An appropriate fee or delegation of archiving responsibilities should be agreed with each NHS Trust and entered into the Industry Costing Template.

#### 5.4 Monitoring visits

Staff time for monitoring visits is included in the per patient budget, as the frequency and length of visits will directly relate to the number of patients enrolled in the study.

### 6. The Timecard

Calculating the costs and ultimately the total price of an industry-sponsored study is achieved by identifying all activities conducted within the study, establishing which member of staff would be most likely to perform the activity and the time required to complete each task. All negotiating parties can then see a clear breakdown of staff costs. Guidance is provided within the Industry Costing Template for estimating the timing of activities in the form of The Time Card.

### **ANNEX 3 How does the NIHR CRN Industry Costing process address the variation of costs for NHS Trusts?**

The Industry Costing Template standardises the rates for staff, investigations and costs for departments supporting research and recognises that the cost of providing facilities to conduct clinical research varies between NHS Trusts. The NIHR CRN have 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.

The PbR MFF ranges from 1.00 at South Devon Healthcare Trust, up to the maximum PbR MFF rating of 1.44 at St Mary's NHS Trust, London. Topic Specific Clinical Research Network (TCRN) adopted industry-sponsored studies were used to pilot the Industry Costing Template and proposed cost elements. However when multipliers over 1.25 (i.e. those relating to the inner London NHS Trusts) were added to the final price in the Industry Costing Template the final sum was considered too high by companies. The participating London Trusts also calculated their prices lower than the price generated using 1.44 and agreed that using the maximum multiplier made inner London Trusts too expensive and therefore less attractive to companies. The Industry Costing Template will be introduced with a PbR MFF cap at 1.25 and this element will be evaluated on an ongoing basis.

The final price calculated within the Industry Costing Template is multiplied by the PbR MFF rating for each individual participating Trust:

For example, a calculated fee per patient of £2500 becomes:  
Nottingham PbR MFF  $1.07 \times £2500 = £2681$  (price for Nottingham)  
London PbR MFF  $1.25 \times £2500 = £3125$  (price for London)

Further information about Payment by Results can be found at the following website:  
[http://www.dh.gov.uk/en/Managingyourorganisation/Financeandplanning/NHSFinancialReforms/DH\\_077279](http://www.dh.gov.uk/en/Managingyourorganisation/Financeandplanning/NHSFinancialReforms/DH_077279)

The PbR MFF applies to English NHS Trusts only. NIHR CRN is working closely with the devolved nations to facilitate the development of compatible systems across the whole of the UK, therefore please contact the Industry Team at NIHR CRN for advice about costing studies outside England.

## **ANNEX 4 The NIHR CRN Industry Costing Group Membership:**

### **NIHR CRN**

- **Clare Morgan**, Assistant Director - Industry
- **Christopher Burdette**, Costing and Contracts Manager - Industry
- **Rick Kaplan**, Associate Director - Industry
- **Joanne Holloway**, Assistant Director, UKDRN
- **Louise Forster**, Research Co-ordinator, UKDRN

### **NHS R&D/University**

- **Maria Palmer**, Director of NHS R&D Forum, Head of R&D, UBHT
- **Gerry Leonard**, Head of Research Resources, Barts and the London Trust and Queen Mary University
- **Jackie Powell**, Director, Joint Clinical Trials Office, KCL, KCH, GS&T
- **John Harrison**, Finance Manager, Kings College
- **Diana Benton**, Commercial Research Manager, UBHT
- **Dawn Lawson**, R&D Manager, Leeds Teaching Hospitals Trust
- **Charles Weller**, Commercial R&D Manager, Dundee
- **Christine McGrath**, Director R&D, Southampton University Hospitals NHS Trust
- **Keith Chantler**, Director of Academic Affairs and Innovation, CMMC
- **Tania Palalic**, Research Services Manager, Imperial College

### **Industry**

- **Peter Bay**, Business Operations Executive, Pfizer
- **Adrienne Clarke**, Study Management Director, GSK
- **Ignazio di Giovanna**, Director, Charles Campbell Associates
- **Debbie Froud**, NIHR CRN Industry Seconded and Project Manager, Lilly

### **Department of Health**

- **Trudi Simmons**, NHS R&D Manager, Department of Health
- **Mark Lewis**, Advisor to the Department of Health

### **Pharmacy Sub-Group**

- **Tim Root**, Specialist Pharmacist, East & South East England Specialist Pharmacy Services (Chair)
- **John Bane**, Sheffield Children's Hospital NHS Trust
- **Peter Bay**, Pfizer
- **Joanna Cattle**, Southampton University Hospitals NHS Trust
- **John Gilroy**, Newcastle University Hospitals NHS Trust
- **Andrew Davies**, Director of Pharmacy, North Bristol Hospitals NHS Trust
- **Ann Jacklin**, Imperial Healthcare NHS Trust
- **David Leonard**, Imperial Healthcare NHS Trust
- **Mark Lewis**, Advisor to the Department of Health
- **Liz Mellor**, Leeds Teaching Hospitals NHS Trust
- **Tony Nunn**, Royal Liverpool Childrens' NHS Trust
- **Maria Palmer**, Director of NHS R&D Forum, Head of R&D, UBHT

We would also like to acknowledge the advice and support of the many other individuals and organisations who have contributed to the development and refinement of the NIHR CRN Industry Costing process.

## ANNEX 5 Glossary

The following terms have been used in this document.

For further information visit the NIHR CRN website

[www.crncc.nihr.ac.uk/index/industry.html](http://www.crncc.nihr.ac.uk/index/industry.html) or contact the NIHR CRN Industry Team at [crncc.industry@nihr.ac.uk](mailto:crncc.industry@nihr.ac.uk) or telephone 0113 343 0341

### **NIHR Adoption**

Companies wishing to run a study through the NIHR Networks must submit the study to the appropriate Network Coordinating Centre for adoption. Adopted studies are part of the NIHR Portfolio, gain access to NIHR network resources and are classed as high priority.

### **Capacity Building**

A 20% capacity building element has been added to direct staff costs and investigation prices. This surplus should be ring fenced by NHS Trusts to build research resources.

### **Contract Trials/ Contract Research**

Contract trials, contract research and industry sponsored studies are the same; they refer to clinical trials sponsored and fully funded by industry.

### **Direct Staff Costs**

Direct staff costs include salary and employer's contributions presented as an hourly rate. They contain no overheads, capacity building or any other increment. For an individual study, the total direct staff costs are calculated by identifying the time required for study specific activities.

### **Investigation Pricing Index**

The index contains investigations which are commonly used in clinical trials and are presented with a price which already includes overheads. Capacity building and PbR MFF will also be added to this price.

### **Overheads**

The term 'overheads' has been specifically used within this project as it is the most commonly used term by both the NHS and industry. Overheads are the indirect running costs incurred by an organisation. They have an impact on all aspects of the organisation's business and include heating, lighting, building maintenance, security, finance, general admin, human resources, corporate management and all other resources which allow the organisation to function. **Overheads are applied to direct staff costs only.**

### **Payment by Results Market Forces Factor (PbR MFF)**

PbR MFF is the multiplier used to create a final price for each individual NHS Trust

### **Per Patient Budget**

The per patient budget is the price calculated for the completion of data for an individual patient within a clinical trial. The price includes overheads and capacity building and is adjusted for each Trust using PbR MFF.

### **Costs for Departments Supporting Research**

These are the costs for departments within an NHS Trust providing specific services for a trial. For example, pharmacy charges or a radiology department set up fee if the trial requires changes in the standard service offered.