Important notice

This document, “NIHR Clinical Research Network: Impact and Value Assessment” has been prepared by KPMG LLP (“KPMG”) solely for University of Leeds in accordance with specific terms of reference (“terms of reference”) agreed between University of Leeds (“the Beneficiary”), and KPMG dated 1 March 2016. KPMG LLP wishes all parties to be aware that KPMG’s work for the Beneficiary was performed to meet specific terms of reference agreed between the Beneficiary and KPMG and that there were particular features determined for the purposes of the engagement.

KPMG does not provide any assurance as to the appropriateness or accuracy of sources of information relied upon and KPMG does not accept any responsibility for the underlying data used in this report.

The document should not be regarded as suitable to be used or relied on by any other party wishing to acquire rights against KPMG (other than the Beneficiary) for any purpose or in any context. Any party other than the Beneficiary that obtains access to this document or a copy (under the Freedom of Information Act 2000, the Freedom of Information (Scotland) Act 2002, through the Beneficiary’s Publication Scheme or otherwise) and chooses to rely on this document (or any part of it) does so at its own risk. To the fullest extent permitted by law, KPMG does not assume any responsibility and will not accept any liability in respect of this document to any party other than University of Leeds.

The opinions and conclusions expressed in this document are those of KPMG and do not necessarily align with those of University of Leeds.
### Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABPI: Association of the British Pharmaceutical Industry</td>
<td>Industry sponsored: all commercial and investigator initiated studies sponsored by industry (i.e. a pharmaceutical company or medical device company)</td>
</tr>
<tr>
<td>ARSAC: Administration of Radioactive Substances Advisory Committee</td>
<td>IRAs: Integrated Research Application System</td>
</tr>
<tr>
<td>CRO: Contract Research Organisation</td>
<td>LCRN: Local Clinical Research Network</td>
</tr>
<tr>
<td>CRN: Clinical Research Network</td>
<td>MHRA: Medicines and Healthcare products Regulatory Agency</td>
</tr>
<tr>
<td>CTA: Clinical Trials Authority</td>
<td>NHS: National Health Service</td>
</tr>
<tr>
<td>CSP: Coordinated System for gaining Permissions</td>
<td>NIHR: National Institute of Health Research</td>
</tr>
<tr>
<td>EU: European Union</td>
<td>NIHR CRN: National Institute of Health Research Clinical Research Network</td>
</tr>
<tr>
<td>FTE: Full Time Equivalent</td>
<td>NOMS: National Offender Management Service</td>
</tr>
<tr>
<td>FY: Financial Year</td>
<td>nRCF: Network Research Capability Funding</td>
</tr>
<tr>
<td>GCP: Good Clinical Practice</td>
<td>ONS: Office of national Statistics</td>
</tr>
<tr>
<td>GVA: Gross Value Added</td>
<td>Other care providers: An inclusive term to account for primary care providers.</td>
</tr>
<tr>
<td>HFEA: Human Fertilisation and Embryology Authority</td>
<td>RCT: Randomised Control Trial</td>
</tr>
<tr>
<td>HSC: Health and Social Care</td>
<td>R&amp;D: Research and Development</td>
</tr>
<tr>
<td>HRA: Health Research Authority</td>
<td>Sponsor companies: An inclusive term for all companies funding commercial research. This includes (but is not limited to) pharmaceutical companies, biotech companies and medical device companies.</td>
</tr>
<tr>
<td>HTA: Human Tissue Authority</td>
<td>UK: United Kingdom</td>
</tr>
</tbody>
</table>
# Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Executive summary</td>
<td>1</td>
</tr>
<tr>
<td>2 Introduction</td>
<td>6</td>
</tr>
<tr>
<td>2.1 Clinical research in the UK</td>
<td>6</td>
</tr>
<tr>
<td>2.2 The context of this study</td>
<td>8</td>
</tr>
<tr>
<td>3 Clinical research in the UK</td>
<td>10</td>
</tr>
<tr>
<td>3.1 Challenges and reforms in the UK clinical research market</td>
<td>10</td>
</tr>
<tr>
<td>3.2 The case for Government support</td>
<td>14</td>
</tr>
<tr>
<td>4 Overview of the CRN’s activities</td>
<td>18</td>
</tr>
<tr>
<td>5 Economic impact of the CRN’s clinical research activity</td>
<td>21</td>
</tr>
<tr>
<td>5.1 A framework to estimate economic impact</td>
<td>21</td>
</tr>
<tr>
<td>5.2 The impact by stakeholder type</td>
<td>23</td>
</tr>
<tr>
<td>5.3 Limitations of our approach</td>
<td>24</td>
</tr>
<tr>
<td>5.4 Results of our economic impact analysis</td>
<td>26</td>
</tr>
<tr>
<td>6 Monetary benefits to NHS Trusts</td>
<td>30</td>
</tr>
<tr>
<td>6.1 Payments to NHS Trusts</td>
<td>30</td>
</tr>
<tr>
<td>6.2 NHS cost saving</td>
<td>33</td>
</tr>
<tr>
<td>7 Added value of the CRN</td>
<td>38</td>
</tr>
<tr>
<td>7.1 Summary of stakeholder responses</td>
<td>39</td>
</tr>
<tr>
<td>7.2 LCRN infrastructure</td>
<td>42</td>
</tr>
<tr>
<td>7.3 CRN Coordinating Centre</td>
<td>45</td>
</tr>
<tr>
<td>7.4 Study setup and site feasibility</td>
<td>46</td>
</tr>
<tr>
<td>7.5 Model templates</td>
<td>48</td>
</tr>
<tr>
<td>8 Action plan</td>
<td>49</td>
</tr>
</tbody>
</table>
8.1 Recommendations for economic impact analysis 49
8.2 Recommendations for average per patient payments 51
8.3 Action plan to estimate the average cost saving to the NHS 52
8.4 Annex to the Action Plan 53

Appendix 1 Technical annex 58

A1.1 Economic impact 58
A1.2 Estimating per patient payment 63
A1.3 Estimating the pharmaceutical cost saving to the NHS 65

Appendix 2 Stakeholder interview questions 68

NHS Trusts 68
Pharmaceutical and Medical Device companies 70
Contract Research Organisations (CROs) 72
Charities 74
CRN personnel 76
1 Executive summary

The importance of clinical research to the UK is recognised by Government\(^1\), but there are challenges to realising the benefits. The National Institute of Health Research (NIHR) Clinical Research Network (CRN) was established to help overcome these challenges and support the successful delivery of clinical research in the UK.

Clinical research in the UK is essential for improving care for patients, providing evidence on the efficacy of new healthcare treatments.\(^2\) Prior to 2006, the UK clinical research environment faced some critical challenges in meeting the commitment in the NHS constitution to “promote, conduct and use research to improve the current and future health and care of the population”.\(^3\)

In response, the Department of Health launched a Government strategy for health research: Best Research for Best Health.\(^4\) A key action of this was to establish the NIHR CRN. The CRN comprises of a central Coordinating Centre and 15 Local Clinical Research Networks which work together to support the initiation and delivery of high-quality research. It provides the infrastructure and study support services that enable clinical research to take place in the NHS.\(^5\)

This report considers the impact and value of the CRN – it considers the economic impact of all clinical research activity supported by the CRN, the monetary benefits to the NHS and the value added by the CRN’s support services.

The CRN has identified a need to demonstrate the impact of clinical research studies brought onto the CRN Portfolio and the value for money delivered. To assist in this, the CRN commissioned KPMG to undertake research and analysis to understand the economic impact of its activities.

In this report, we consider the role for Government support in the clinical research market and the regulatory challenges facing the industry. We quantify the economic impact of the activities within the CRN research portfolio as well as the other monetary benefits to NHS Trusts. These include the revenues received from sponsor companies due to commercial studies as well as cost saving to the NHS due to pharmaceuticals provided for free for commercial studies.

This KPMG report estimates that in financial year (FY) 2014/15, CRN supported clinical research activity generated £2.4 billion of gross value added (GVA) and almost 39,500 jobs in the UK.


\(^4\) NIHR. 2016. ‘History of the NIHR’. Available at: http://www.nihr.ac.uk/about/history-of-the-nihr.htm

\(^5\) NIHR CRN. 2016. ‘Study Support Services’. Available at: https://www.crn.nihr.ac.uk/can-help/study-support-service/
We assess economic impact in terms of GVA which is a measure of the contribution of an individual investment, producer, industry or sector to the economy. It is the value of outputs from production minus intermediate consumption (the value of the goods and services consumed as inputs to the production process).

The analysis is based on standard economic impact methodology set out in HM Treasury’s Green Book and draws on Office for National Statistics guidance on the calculation of gross value added.

We also estimate the employment impact in terms of the number of jobs created as a result of the CRN-supported clinical research activity. We estimate that in the period April 2014 to March 2015 (FY 2014/15) clinical research activity supported by the CRN generated a total of £2.4 billion GVA and almost 39,500 jobs. This includes £778 million as a result of non-commercial activity, £1.6 billion due to commercial activity and £21 million as a result of the CRN’s Coordinating Centre’s activities. This includes the direct GVA and employment impacts, as well as those generated in the supply chain and the wider economy. These impacts are summarised below.

---


8 Non-commercial studies are conducted by researchers not funded by commercial companies. These studies are usually paid for with grant funding from charities, Government or other not-for-profit organisations.

9 Commercial research is defined as research that is funded and sponsored by a commercial organisation, such as a pharmaceutical company or a Medical Device company. This can also include investigator initiated trials, which is research funded by a commercial company but where a NHS Trust or another non-commercial organisation retains the intellectual property rights and/or is the sponsor of the study.
In addition to the economic impact of clinical research activity, we the NHS benefits from additional revenues and cost savings, totalling an estimated £192 million.

We found that, for commercial studies, NHS Trusts receive an average of £6,658 in revenue from sponsor companies, and a pharmaceutical cost saving of £5,250 per patient recruited to each clinical study. This equates to estimated totals of £176 million of commercial income and £16 million of pharmaceutical cost savings across the commercial CRN Portfolio for FY 2014/15.

---

10 For the CRN Coordinating Centre the employment figure is made up of 170 direct FTE jobs and 113 FTE jobs generated in the supply chain and wider economy.
Our analysis is based on data from a range of sources, including information provided directly by NHS Trusts and the CRN, publically available data on the commercial industry, non-commercial funding information, and the application of evidence based assumptions. Most significantly, challenges in obtaining relevant data from NHS Trusts means that our estimates are based on data relating to a sample of sites, scaled up to provide an estimate of the impact across the CRN Portfolio of studies. While the sample provides broad geographical and specialty coverage, it should not be considered a representative sample. The figures in this report should therefore be considered indicative of the expected impact of the clinical research activity supported by the CRN, rather than being exact measures.

*There are also a number of additional impacts of the CRN that generate significant benefits for the market that are not quantified.*

To understand these impacts, we consulted with 40 stakeholders selected in collaboration with the CRN to ensure coverage of all stakeholder-types – sponsor companies, NHS Trusts, CRN, LCRN and charities. Consultation was confidential and all reporting has been done in aggregate. The key messages from stakeholders are summarised below.

— The CRN has paved the way for a higher profile of the clinical research market in the UK which has attracted commercial attention.

— The LCRN infrastructure (the ‘frontline’ staff) is integral to the delivery of clinical research, particularly for non-commercial studies.
— Staff involved with CRN clinical research benefit from training offered by the CRN. This represents a sizable cost saving to NHS Trusts and other care providers.

— The CRN has improved study set-up time and processes. The pace with which recruitment can commence after study set-up was cited as a benefit of the CRN support and infrastructure.

— The CRN enables greater access for sites and patients. Sponsor companies pointed out the CRN introduced them to sites they otherwise would not have reached out to.

— The use of CRN costing templates and model agreements has process efficiencies for some stakeholders and positive impacts on the market in terms of transparency in pricing.

— Collaborative benefits, such as sharing of best practice and the use of CRN specialty leads to enhanced collaboration, was noted as a significant added-value.

— The independence of the Coordinating Centre to monitor performance and allocate funding is a benefit for the market and provided a ‘critical friend’.

— There are also a number of wider positive benefits in particular benefits to infrastructure, the learning and skill development of clinicians, improved quality of care and health outcomes for patients as well as quicker uptake of new treatments in the UK.

These impacts, although not easily quantified, are seen by stakeholders as critical to the successful deliver of effective clinical studies in the UK. Looking forward, stakeholders said the CRN should prioritise input from a local level regarding clinical research pipeline planning, undertake further patient engagement activity as well as consider how value can be delivered in the future beyond establishing working relationships between stakeholders. Sponsor companies and NHS Trusts stated, in establishing these relationships, the CRN had been integral. However, going forward the value was going to be derived from building on these relationships.

*This study provides a baseline of the economic impact of the CRN. Going forward, the CRN wishes to carry out ongoing monitoring and evaluation to measure the impact and value of its activity.*

For several data sources used in this report, data extraction has been a resource intensive process and in some areas the available data has not been comprehensive. This is the result of the following issues:

— difficulty for NHS Trusts to provide data. This is primarily because data is usually held in a non-aggregate form by NHS Trusts so extraction is resource intensive.

— commercial sensitivity regarding provision of data for sponsor companies, CROs and for NHS Trusts (relating to commercial studies).

We have consolidated the lessons learned from data collection as part of the report to produce a proposed action plan setting out what data are needed in order to carry out a similar exercise in the future and how they can best be captured, taking into account the data availability and resource limitations we have identified as part of this report.
2 Introduction

2.1 Clinical research in the UK

Clinical research undertaken in the UK provides evidence on the efficacy of new healthcare treatments. It helps the NHS to improve the care given to patients.\textsuperscript{11}

Patients benefit from clinical research, in particular through the additional treatment options that it makes available to them.\textsuperscript{12} Recognising this, the NHS Constitution\textsuperscript{13} commits to the “promotion, conduct and use of research to improve the current and future health and care of the population” and to ensure patients from every part of England are made aware of research that is of relevance to them.\textsuperscript{14}

However, historically, the routes through which clinical research was conducted and funded were complex. Between 1990 and 2006, a number of reviews and reports identified challenges to the UK health research environment in England.\textsuperscript{15} In response, the Department of Health launched a Government strategy for health research: Best Research for Best Health.\textsuperscript{16} A key action as part of the strategy was to establish a National Institute for Health Research, which subsequently launched in April 2006, to centralise research activity support services – to do this, the NIHR provides infrastructure, faculty, research and systems.\textsuperscript{17} The NIHR CRN\textsuperscript{18} was created too as part of the infrastructure of this support.\textsuperscript{19}

The CRN’s remit is to support the delivery of high-quality clinical research in the NHS. Its purpose is to provide efficient and effective support for the initiation and delivery of funded research in the NHS. Some of this research is funded by the NIHR, but most is funded by NIHR non-commercial partners\textsuperscript{20} and industry.\textsuperscript{21}

The CRN’s structure includes:

— the Coordinating Centre, the central study support resources that manage performance data submissions, facilitate training and a range of activities across the UK; and,

\begin{footnotes}
\item[11] Quote from Professor Dame Sally C Davies, Chief Medical Officer, NIHR.
\item[12] NIHR CRN. 2016. ‘Why engage in research?’ Available at: https://www.crn.nihr.ac.uk/can-help/healthcare-professionals/why-engage-in-research/
\item[15] NIHR. 2016. ‘History of the NIHR’. Available at: http://www.nihr.ac.uk/about/history-of-the-nihr.htm
\item[17] NIHR. 2016. ‘Structure of the NIHR’. Available at: http://www.nihr.ac.uk/about/structure.htm
\item[18] Hereafter the NIHR CRN will be referred to as the CRN
\item[19] Infrastructure provides the facilities and people for a thriving research environment, faculty supports individuals carrying out and participating in research, research involves commissioning and funding and systems involves creating unified, streamlined and simple systems for managing research and its outputs. See: NIHR. 2016. ‘History of the NIHR’. Available at: http://www.nihr.ac.uk/about/history-of-the-nihr.htm
\item[20] Non-commercial partners are those organisations that award research funds as a result of open competition across England with high quality peer review, fund research that is of clear value to the NHS and take appropriate account of the priorities, needs and realities of the NHS in making decisions about the research they fund. See: https://www.crn.nihr.ac.uk/wp-content/uploads/Funders%20academics/NIHR%20Partner%20List/NIHR%20Partner%20List.pdf
\end{footnotes}
— 15 Local Clinical Research Networks who provide on-the-ground infrastructure to assist with the delivery and recruitment for studies.

These are collectively referred to as the CRN unit in this report and both work together with shared principles, values and behaviours. It funds research posts in the NHS, provides training to front-line staff, provides funding to meet the costs of some research facilities as well as providing practical help in identifying and recruiting patients.

Those clinical research studies that meet the specified eligibility criteria are added onto the CRN Portfolio of studies and are able to receive study support from the CRN. Between April 2014 and March 2015, a total of 1,869 new studies were added to the CRN Portfolio, with over a third of these sponsored by commercial companies. In the same year, 618,453 patients were recruited onto Portfolio studies, representing just over one per cent of the population of England.

Whilst it is difficult to estimate the exact proportion of all England-based clinical studies supported by the CRN due to the lack of comprehensive data covering all UK studies, there are some sources which provide an indication of this proportion. Based on these sources we estimate that the CRN supports around 70 per cent of all clinical research studies (including those which are ineligible for funding).

The EU Clinical Trials Register is a compulsory register for all pharmaceutical-based interventional studies, and provides data on studies conducted in the UK. Based on this database, we estimate that the equivalent studies on the CRN Portfolio make up around 50 per cent of all pharmaceutical-based studies undertaken in the UK.

The MHRA also holds a record of all Clinical Trial Authorisation (CTA) approvals, which are required for all investigational studies of medicinal products carried out in the UK. The MHRA estimates that 88 per cent of studies it approves are supported by the CRN.

Information gathered directly from stakeholders as part of this study suggests that the overall proportion falls somewhere between these estimates, and suggests that the CRN provides support to around 70 per cent of all clinical research studies. Information from stakeholders suggests that the figure is higher for commercial studies (estimated at 90 per cent) than for non-commercial studies (estimated at 60 per cent). However, the proportion of non-commercial studies supported by the CRN would be expected to be higher if ineligible studies (including most PhD studies) were excluded from the total.

23 NIHR CRN. 2015. ‘Key statistics’. Available at: https://www.crn.nihr.ac.uk/about-crn/our-performance/key-statistics-2/
24 Based on a comparison of studies registered on EU Clinical Trials Register (only pharmaceutical-based interventional trials required to register) versus those on the Portfolio (pharmaceutical-based interventional trials to match EU Clinical Trials Register eligibility criteria). This proportion has remained relatively stable since 2013. KPMG estimates show a jump in the proportion of trials covered by the CRN from 2012 (38%) to 51% in 2013. In 2014, this proportion was 53% and in 2015 was 50%.
25 This covers Phase 2-4 commercial studies for which the MHRA is required to give approval for.
26 We requested information from all LCRNs regarding the number of Portfolio and non-Portfolio studies for both commercial and non-commercial research. We received data from seven NHS Trusts regarding this and our estimate is based on this.
27 Stakeholders (predominantly NHS Trusts) indicated data could not be disaggregated to exclude PhD studies for this estimate.
2.2 The context of this study

The CRN was allocated £284.6 million for FY 2014/15 and FY 2015/16 by the Department of Health to support its activities and infrastructure.

In 2015/16 the CRN also received Network Research Capability Funding (nRCF) of £9.9m from the Department of Health. Of this approximately £6m of "flow-through" funding was allocated with the intention of incentivising success in commercial studies.28

For 2016/17, nRCF will no longer be allocated. Instead the CRN has been allocated core funding of £290.6m, made up of flat funding of £284.6m from the previous core allocation, together with £6m provided specifically for the commercial incentivisation "flow-through" element.

This funding allocation supports clinical research posts in the NHS, and provides the required training, so that researchers benefit from access to experienced ‘front-line’ staff who support the delivery of studies. The funding also provides for the costs of using facilities (such as scanners and x-rays) needed in the course of clinical research and practical help in identifying and recruiting patients onto Portfolio studies.

Going forward, the CRN needs to demonstrate the impact of clinical research studies brought onto the CRN Portfolio and the value for money delivered. This is particularly important in the current climate of fiscal austerity. In particular, HM Treasury and Government departments are putting a greater focus on the financial and economic returns to Government spending.29 However, evidence of the value and impact of clinical research in the UK is difficult to quantify, and in particular the specific contribution of the CRN. To assist in building this evidence base, the CRN commissioned KPMG to undertake research and analysis to understand the economic impact of its activities.

In particular, the CRN asked KPMG to assess:

1. The economic contribution made to the UK economy through clinical research activity supported by the CRN;
2. A measure of the payments made to NHS Trusts for commercial studies; and
3. The value to the NHS of pharmaceuticals used as part of industry-sponsored studies.

This study focuses on the immediate economic and wider impacts generated from clinical research activity itself, rather than the outcomes of the research. We also examine the role of the CRN and the value it adds to the clinical research market.

This report is structured as follows:

— We first consider the overall economic impact, in terms of gross value added (GVA)30 and employment generated through the CRN Portfolio of clinical research studies.

---

28 Financial information provided by the NIHR CRN for the purposes of this report.
30 GVA is a measure of contribution to GDP. It is output minus intermediate consumption and shows the additional contribution to the economy of the industry. It is a key component of gross domestic product (GDP) which is a measure of the value of production and the state of the economy.
— We then quantify other monetary benefits to the NHS resulting from clinical research activity. This includes cost savings from pharmaceutical products provided free by sponsor companies as well as commercial income payments to NHS Trusts.

— Next, we consider the value added by the CRN within the clinical research market. We consider the wider benefits and contributions made by the CRN and, in particular, its additionality (i.e. the net impact after making allowances for what would have happened in its absence).

— Finally, since this analysis may serve as a baseline for future assessments by the CRN and for other impact studies, we present an Action Plan recommending what data should be collected going forward to help measure the CRN’s future economic contribution.
3 Clinical research in the UK

3.1 Challenges and reforms in the UK clinical research market

The UK is an established market for clinical research. The global market for clinical research is estimated to be worth £38 billion ($63 billion).\(^{31}\) The UK is a prominent location for this activity. In FY 2014/15, total health related R&D spending (both commercial and non-commercial) was estimated to be in the region of £8.5 billion.\(^{32}\) Of this:

— 48 per cent of this was spent by commercial companies;
— 32 per cent by higher education providers;
— 15 per cent by public sector research institutes; and
— 5 per cent by the private non-profit sector.

Over the past five years, there appears to have been an overall increase in the volume of studies, but the picture is mixed across phases of study and clinical specialties.

Looking across a range of data sources\(^{33}\), there appears to have been a small increase in the total number of clinical studies carried out in the UK over the last five years, there is an inconsistent picture across sources, none of which provide a comprehensive view. There is also a mixed picture in terms of growth in the volume of clinical research studies across different phases of study and in different clinical specialties with some seeing growth, whilst other have seen a decline.

MHRA data shows this ‘mixed growth’ picture indicating growth varies by phase. Data of approved studies, as per MHRA records, suggests that since 2010 there has been a decline in Phase 1 and Phase 4 study applications, while the number of Phase 2/3 applications has grown.\(^{34}\)

\(^{31}\) As at 2014, figure has been discounted using 2014 USD to GBP exchange rate. Pharm Source. Icon Plc January 2016. Presentation at JP Morgan Conference. Available at: http://www.pharmsource.com/market/how-big-is-the-market-for/#Clinical Research Total

\(^{32}\) UK CRC. 2015. ‘UK Health Research Analysis, 2014’. Available at: http://www.ukcrc.org/research-coordination/health-research-analysis/uk-health-research-analysis/

\(^{33}\) This includes the EU Clinical Trials Register, Thomson Reuters reported by ABPI, approval data from the MHRA and clinicaltrials.gov. All these sources contain information about different types of studies (for example, EU Clinical Trials Register only includes data for interventional pharmaceutical based studies).

Figure 3: Applications received by MHRA, by phase for interventional studies using a pharmaceutical product

Source: MHRA. 2014. No data for 2015 has currently been released.

Showing a similarly mixed picture across clinical specialties, the Association of the British Pharmaceutical Industry (ABPI) reports on therapeutic focus where the UK has historically performed strongly compared with other European countries. It finds that the UK has seen a small growth in commercial oncology studies since 2010 while over the same time period, commercial studies relating to the nervous system and cardiovascular treatments have declined.35

However, the UK has remained competitive in these fields relative to its European neighbours and the UK has gained competitive strength against Germany and France in particular.36

The UK and Europe have faced increasing competition from a growing number of global competitors.37

The UK is facing increasing competitive pressure due to a growing number of global competitors, predominantly from China and Brazil (in East Asia and South America).38 Growth in the market share in these regions and the subsequent increase in expertise means companies can now confidently undertake commercial clinical research studies in less historically established markets. The change in the number of clinical research studies across different regions globally can be seen in Table 1. Most regions have experienced growth in the number of clinical research studies, with the most significant growth seen in Asia and the Americas.39

39 Novak, T., Payeur, G., Belotserkovsky, M. 2014. 'Decline of Clinical Trials in Central and Eastern Europe: Fluctuation or Trend?' Applied Clinical Trials.
The market share of the UK has declined as a result of this expanded marketplace. This competitive pressure is considered to be mainly based on cost efficiencies, the burden of set-up, quality of health care facilities and the size of the potential patient pool.

Views from Contract Research Organisations (CROs) and sponsor companies consulted as part of our study reflects this competitive pressure. Half of those we spoke to reported that the proportion of global studies allocated to the UK over the past five years has decreased or not changed.

To remain competitive, the UK has made significant improvements to the regulatory environment, making it more competitive and attractive to commercial companies.

In January 2011, the Academy of Medical Sciences published its regulatory and governance review of health research: *A new pathway for the regulation and governance of health research*. The review made a number of recommendations to transform the regulatory environment in the UK, to reduce the time taken to set-up studies and to facilitate research.

In response, the Government, in its 2011 *Plan for Growth*, announced the creation of a new single health research regulatory agency to streamline regulation and improve the cost effectiveness of studies.

The Health Research Authority (HRA) was established in December 2011 to promote patient health and streamline regulation. The HRA approval comprises a review by a Research Ethics Committee as well as an assessment of regulatory compliance and related matters. This replaces the need for local checks of legal compliance and related matters by each participating organisation (or site) in England. For researchers, this has meant elimination of duplicate application routes, a reduction of paperwork and an overall shortening of time to complete the approvals process.

### Table 1: Clinical research growth by region

<table>
<thead>
<tr>
<th>Region</th>
<th>Relative change in number of studies between 2006 and 2012 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Africa</td>
<td>30.77</td>
</tr>
<tr>
<td>Central America</td>
<td>-14.77</td>
</tr>
<tr>
<td>East Asia</td>
<td>217.57</td>
</tr>
<tr>
<td>Japan</td>
<td>94.58</td>
</tr>
<tr>
<td>Europe</td>
<td>32.36</td>
</tr>
<tr>
<td>Middle East</td>
<td>40.37</td>
</tr>
<tr>
<td>North America</td>
<td>36.17</td>
</tr>
<tr>
<td>North Asia</td>
<td>15.29</td>
</tr>
<tr>
<td>Pacifica</td>
<td>-14.85</td>
</tr>
<tr>
<td>South America</td>
<td>45.90</td>
</tr>
<tr>
<td>South Asia</td>
<td>45.90</td>
</tr>
<tr>
<td>Southeast Asia</td>
<td>42.62</td>
</tr>
</tbody>
</table>

Source: Novak et al. 2015.
The Integrated Research Application System (IRAS) is a single system for applying for the permissions and approvals for health and social/community care research in the UK. This is a single point of entry for permissions, which vary depending on the type of clinical research (see Box 1 below for more detail).

**BOX 1: REVIEW BODY APPROVALS REQUIRED FOR CLINICAL RESEARCH**

The regulation of health research provides participants with assurance that research is of high quality, safe and ethical. To do this, there are various types of approvals relevant for different types of research. These are briefly summarised below and are all accessed from the IRAS.

1. **HRA Approval** – a review by a NHS Research Ethics Committee and assessment of regulatory compliance and related matters.

2. **NHS management permission in Scotland, Wales or Northern Ireland** – researchers who wish to conduct research in the NHS in Wales or Scotland, or Health and Social Care (HSC) in Northern Ireland must obtain NHS (or HSC) management permission.

3. **Research Ethics Committee** – review applications for research and given an opinion about the proposed participant involvement and whether the research is ethical. There are various different types of REC.

4. **Medicines and Healthcare products Regulatory Agency (MHRA) – clinical trial authorisation (Investigational Medicinal Products)** – a Clinical Trial Authorisation (CTA) is required for any clinical trial of an investigational medicinal product to be conducted in the UK.

5. **Medicines and Healthcare products Regulatory Agency (MHRA) – Notice of No Objection (Medical Devices)** – an application to MHRA Devices is required where the study is a clinical investigation of a medical device undertaken by the manufacturer.

6. **Confidentiality Advisory Group** – provides independent expert advice to the HRA and the Secretary of State for Health on whether applications to access confidential patient information without consent should or should not be approved.

7. **National Offender Management Service (NOMS)** – if the project is with Prisons or Probation Trusts, an application to NOMS will be required.

8. **Administration of Radioactive Substances Advisory Committee (ARSAC)** – for research involving administration of radioactive materials which are additional to normal care.

9. **Human Fertilisation and Embryology Authority (HFEA)** – for research involving human embryos and gametes.

10. **Human Tissue Authority (HTA)** – under the Human Tissue Act 2004, storage of material from a human body consisting of or including cells for scheduled purposes.

Source: HRA. 2016. Available at: http://www.hra.nhs.uk/research-community/before-you-apply/determine-which-review-body-approvals-are-required/

Alongside these UK-based changes, there have also been reforms to relevant EU legislation. The EU Clinical Trials Directive (CTD) was adopted in 2001. The new directive was seen as controversial and was criticised by sponsor companies, researchers and a range of stakeholders due to its disharmonised interpretation across EU countries, high associated costs, delays and the administrative and regulatory burdens of doing clinical studies in different member states. It was found that from 2007 to 2011 the number of applications to carry out clinical studies in the EU fell by 25 per cent, set-up costs increased significantly and the occurrence of delays to the launching of studies rose by 90 per cent.

---

49 Parliament UK. 2013. ‘Barriers to conducting trials in the UK’. Available at: http://www.publications.parliament.uk/pa/cm201314/cmselect/cmsctech/104/10406.htm

50 Pharmafile. 2015. ‘What you need to know about the EU Clinical Trial Regulation’. Available at: http://www.pharmafile.com/news/198121/what-you-need-know-about-eu-clinical-trial-regulation

The EU Clinical Trial Regulation has since replaced the EU CTD and entered into force on 16 June 2014. Key provisions include:

— a new streamlined process to authorise the launch of new clinical studies based on the submission of a single application;
— introducing a lighter regulatory regime for studies conducted with medicines already authorised and which pose only a minimal risk compared to normal clinical practice;
— simplify reporting requirements sparing researchers from submitting largely identical information on the conduct of the study separately to various bodies; and
— recognise that a study can be led by more than one organisation, formally introducing the term ‘co-sponsorship’.

The new regulation aims to address the shortcomings of the EU CTD, speeding up the process for authorising new clinical studies and reducing the administrative burden associated with conducting studies.

**Despite these significant improvements, there remain challenges for the UK clinical research market.**

The UK continues to face competitive pressure from its European neighbours (particularly Germany, France and Poland) and, more substantially, from global competitors with cost advantages. Changes to the UK regulatory environment since 2011 have gone some way to enable growth in UK clinical research, however this comparative advantage is likely to be challenged by other countries also implementing reforms and incentives to attract research. Continued Government support will be valuable in this space to attract further research and provide services to overcome any barriers due to the research environment.

The UK’s planned exit from the EU has also created uncertainty for the clinical research market. The ABPI has warned Brexit could affect patient access to clinical research as well as uncertainty around the regulatory landscape.52 The ABPI states UK studies could face delays as sponsor companies would deprioritise the UK for a more harmonised approach inside the EU. Some sponsor companies have also warned of the impact, calling for the UK to provide certainty regarding how it would replace European regulations or risk delays in developing crucial medicines.53

### 3.2 The case for Government support

*The nature of the clinical research market means that, despite improvements to the regulatory environment, there remains a role for Government.*

Although there have been significant improvements to clinical research regulations to minimise regulatory barriers in the UK, there still exist challenges to study start-up, information asymmetries regarding site feasibility, barriers to collaboration amongst stakeholders and positive spillovers from clinical research that mean that without Government support there will be underinvestment in effective clinical research.54

---

52 ABPI. 2016. ‘Patient access to medical innovation under threat from Brexit’. Available at: [http://www.abpi.org.uk/media-centre/newsreleases/2016/Pages/Patient-access-to-medical-innovation-under-threat-from-Brexit.aspx](http://www.abpi.org.uk/media-centre/newsreleases/2016/Pages/Patient-access-to-medical-innovation-under-threat-from-Brexit.aspx)

53 Financial Times. July 2016. ‘Roche chief warns of Brexit impact on UK medical research’. Available at: [http://www.ft.com/cms/s/0/4b57010ca-4f14-11e6-88c5-db03e9996900.html#axzz4FQxdsWDe](http://www.ft.com/cms/s/0/4b57010ca-4f14-11e6-88c5-db03e9996900.html#axzz4FQxdsWDe)

54 These all represent market failures which prevent the market delivering an efficient outcome without intervention. See HM Treasury’s Green Book.
recognition of this, in 2006 the CRN was established as part of the wider NIHR organisation following the Government’s strategy for health research: *Best Research for Best Health*.

This section explores why Government support is necessary in the UK clinical research market and how the ways in which the CRN provides this support.

---

**BOX 2: THE ECONOMIC RATIONALE FOR GOVERNMENT SUPPORT**

Before Government takes any action to support or intervene in a market, there must be a clear need which it is in the national interest for Government to address. The underlying rationale would be either on efficiency grounds (where the market does not itself deliver the most efficient outcome) or equity grounds (where Government has distributional objectives).

The rationale for intervention on efficiency grounds is generally the result of a “market failure”. A “market failure” is the inability of a market economy to reach certain desirable outcomes. Market failures can occur for a number of reasons. These are summarised below:

- **Externalities**: this refers to any unintended consequences of market activities that are not properly priced by the market. For example, pollution. A firm producing goods or services may pollute the atmosphere but would not pay for the cost of this pollution. Externalities can be negative (like pollution) or positive. Clinical research would be an example of the existence of positive externalities in the form of positive health benefits, with the market price and returns to research not accounting for the future potential benefits to society from clinical research.

- **Co-ordination problems**: these are most likely to occur when there are a large group of stakeholders who: are heterogeneous; have unknown shared interests; have high initial costs of co-ordination; or, no incentive or mechanism in place to facilitate information sharing or co-ordination.

- **Imperfect information**: this occurs when important information is not well distributed or understood by stakeholders in the market. Information can be ‘asymmetrical’ meaning it is unevenly spread across market participants. For example, one stakeholder has full information and knows the full quality of a good or service and in comparison another does not know its true quality or value. In this instance, the latter stakeholder has a disadvantage in the market and the market will not operate optimally.

- **Imperfect competition**: this occurs when there are few players in a market they have more power than in cases where there are many players. This means they can set their own prices or block other players from entering the market. This is known as imperfect competition.

These are all examples of market failure and are instances which can justify Government intervention or support. This is usually in the form of regulation or subsidies and taxation. It can also be monitoring the market or the provision funding. The type of intervention will vary on the context and what is considered to be most appropriate to the sector.

In the instance of the clinical research market, the most relevant market failures are the presence of positive externalities, co-ordination problems and imperfect information.

*Source: New Economics Foundation and Greater London Authority.*

---


There are co-ordination challenges across stakeholder groups in identifying appropriate sites. In the absence of Government support, there are information asymmetries regarding site feasibility.

For sponsor companies, information asymmetries exist regarding site feasibility – this takes into account the appropriateness of local patient pools, resources constraints due to demands from existing studies as well as information on specialty expertise. Without Government support, there is a risk sponsor companies would continue to return to the same sites for clinical research with little opportunity for other sites and patients to participate.

The impact of this could be twofold. Firstly, there is a risk clinical research could be concentrated in particular geographical areas in the UK. Access to clinical research for a greater number of sites and patients across the UK is beneficial to allow equal access for all patients as well as a more representative patient pool. Secondly, sponsors would be less able to identify the best sites to conduct studies in terms of the appropriateness of the patient pool and the expertise of clinicians. As a result, studies may not achieve their optimal outcome.

The CRN is uniquely placed to overcome these information asymmetries, enabling greater co-ordination between stakeholders in the market.

Delays to study start-up influence location decisions by sponsor companies. Minimising these ensures the UK is competitive globally.

Study start-up is a main factor influencing location decisions, but has been viewed as labour intensive, costly and time-consuming. Ensuring the UK achieves quick start-up times is important to maintain its global competitiveness.

Improvements to regulatory processes have reduced time delays, although there remain factors that can also influence the extent to which these delays occur. These include resource constraints at a site level or delays with negotiations in contracts between sites and funders. Without external support, these competing priorities would mean a higher chance of delays in study start up.

The CRN provides significant support with study start-up and site feasibility. For example, by providing model templates for contractual agreements and costing, providing site feasibility insights and LCRN frontline staff. One of the CRN’s high level objectives is to reduce the time taken for eligible studies to achieve NHS Permission through the Coordinated System for gaining NHS Permission (NIHR CSP). Recent performance data shows that 79 per cent of eligible studies are obtaining these permissions within 40 calendar days. This is an

59 Confirmed from stakeholder engagement with sponsor companies and NHS Trusts as part of this report.
60 Schimanski, C. 2013. ‘Streamline and Improve Study Start-Up’. Available at: http://www.appliedclinicaltrialsonline.com/streamline-and-improve-study-start
63 The CSP is the system which standardises and streamlines the process of gaining NHS Permission (also known as R&D approval) for commercial or non-commercial clinical research studies in England. See: https://www.crn.nihr.ac.uk/wp-content/uploads/Funders%20academics/CSP%20-%20guide%20for%20researchers.pdf
64 NIHR CRN. 2016. ‘NIHR CRN High Level Objectives Year End Performance Report – 2015/16’. 
improvement from 2010 where the median time was 92 days.\textsuperscript{65} Government support in this space ensures the UK remains competitive with setup times.

There are also benefits from collaboration – in the absence of Government support there is a lack of incentives for this to take place.

Clinical research is a highly collaborative process\textsuperscript{66} and the benefits from collaboration in the clinical research market are significant. These include the sharing of best practice, knowledge and expertise. At the individual organisation level, there is a lack of the incentive or ability to implement these practices, but through external (Government) support the benefits of these network effects can be realised.\textsuperscript{67}

The CRN has undertaken a number of engagement activities to enable such collaboration. For example, in 2012, the CRN piloted the Funder Engagement Programme with 12 funding bodies to explore how collaboration between researchers and sponsors at the beginning of research could minimise delivery problems allowing for a more integrated research environment.\textsuperscript{68} Initiating this sort of collaboration is a key benefit from the Government support within the market.

Wider spillover benefits also exist, including increased expertise within NHS Trusts and improved treatment pathways. Government support is needed to ensure these can be realised.

There are also wider spillover benefits\textsuperscript{69} generated from clinical research activity. For example, increased expertise within NHS Trusts benefits patients who are not directly involved with the research and improved treatment pathways and adoption of new treatments benefits future patients.

Left to the market, the decisions to invest in commercial research do not fully take into account the wider social impacts of clinical research, meaning that the level of investment would be below the socially optimal level. Government funding and support is required to encourage further activity to realise these wider spillovers benefiting the market and UK patients.

In the absence of Government support, there would be a lack of collaboration, knowledge sharing or efficiencies from consistent processes.

The CRN plays an important role in ensuring the full benefits of clinical research are realised. The following section further describes the CRN’s activities and the support services it provides to the UK clinical research market.


\textsuperscript{66} Stakeholder conversation held with a charity for the purposes of this report.

\textsuperscript{67} Klemperer, P. 2005. ‘Network Effects and Switching Costs’. Available at: http://www.nuff.ox.ac.uk/users/klemperer/NewPalgrave.pdf

\textsuperscript{68} NIHR CRN. 2012. ‘Making research more realistic’. Available at: https://www.crn.nihr.ac.uk/wp-content/uploads/Funders%20academics/Funder%20engagement%20programme%20article.pdf

\textsuperscript{69} Spillover benefits relate to benefits that spill over to a third party who were not part of the activity. Positive externalities refer to spillover benefits.
4 Overview of the CRN’s activities

The CRN is a unique model internationally, providing 15 local networks and a national Coordinating Centre that together support clinical research delivery and performance. It was set up to enable a world-class health research system in the UK, with high-quality clinical studies.

The CRN is led nationally by a Coordinating Centre and operates through 15 Local Clinical Research Networks (LCRNs) that support the delivery of research within the CRN Portfolio across 30 clinical specialties which encompass all clinical areas in the NHS.

The CRN Portfolio includes both commercial, non-commercial studies and industry-supported studies.

In 2015/16, 1,787 new studies were added onto the CRN Portfolio. Of these, 650 were commercial and 1,137 were non-commercial. The number of open studies on the Portfolio for 2015/16 was 5,185 studies (1,113 commercial and 4,072 non-commercial).

Using data collected by KPMG from a number of NHS Trusts, we estimate that this represents approximately 62 per cent of all non-commercial studies in the UK and 88 per cent of all commercial studies.

Using an alternative source of information to estimate this proportion (the EU Clinical Trials Register for the UK) suggests that overall, for both commercial and non-commercial interventional studies, the CRN Portfolio makes up roughly 50 per cent of all interventional studies by volume. This proportion is lower than the estimates we have gathered from NHS Trusts. This is likely to be due to the inclusion of PhD studies, which are not usually eligible for CRN support, within the EU Clinical Trials Register.

---

70 These local networks cover the whole of England. North East and North Cumbria; North West Coast; Yorkshire and Humber; Greater Manchester; East Midlands; West Midlands; West of England; Thames Valley and South Midlands; Eastern; Kent, Surrey and Sussex; Wessex; South West Peninsula; North Thames; South London; and North West London.

71 Commercial research is defined as research that is funded and sponsored by a commercial organisation, such as a pharmaceutical company or a Medical Device company. This can also include investigator initiated trials, which is research funded by a commercial company but where a NHS Trust or another non-commercial organisation retains the intellectual property rights and/or is the sponsor of the study.

72 Non-commercial studies are conducted by researchers not funded by commercial companies. These studies are usually paid for with grant funding from charities, Government or other not-for-profit organisations.

73 Industry sponsored studies are conducted or initiated by researchers but benefit from funding from commercial companies.

74 We requested information from all LCRNs regarding the number of Portfolio and non-Portfolio studies for both commercial and non-commercial research. We received data from seven NHS Trusts regarding this and our estimate is based on this.

75 EU Clinical Trials Register. 2016. Available at: https://www.clinicaltrialsregister.eu/ctr-search/search

76 Based on a comparison of studies registered on EU Clinical Trials Register (only pharmaceutical-based interventional trials required to register) versus those on the CRN Portfolio (pharmaceutical-based interventional trials to match EU Clinical Trials Register eligibility criteria).
There are key eligibility criteria that commercial and non-commercial research studies must meet to qualify for CRN support.

1) The study must have a clear research question that applies systematic and rigorous methods.
2) It must already have full research funding that meets all of its research costs.

Most non-commercial studies are automatically eligible for CRN support if funded by NIHR non-commercial Partners. Key to this criteria is that the research funding is awarded as a result of open competition across England with high quality peer review, that it funds research that is of clear value to the NHS and that the priorities, needs and realities of the NHS are considered.

Other non-commercial and commercial studies are also potentially eligible. This includes:

- investigator initiated, commercial-collaborative studies;
- non-commercial studies funded by overseas governments;
- non-commercial studies funded by overseas charities; and,
- other high quality studies.

Due to this criteria for non-commercial studies, studies undertaken by PhD candidates are usually not eligible for CRN support. This is important to note when comparing the volume of studies in the CRN Portfolio and in the UK in general.

Commercial contract research is also eligible for support if it meets the definition of ‘research’ and receives NHS Research Ethics Committee approval and NHS permission prior to initiation at individual sites. Commercial studies that are eligible for CRN support require full funding from industry.

The Coordinating Centre and LCRNs provide assistance with establishing the feasibility of studies, such as early feedback on protocol development, site identification and site intelligence. It also supports study setup and performance management.

As well as administrative support and advice, the CRN provides infrastructure to deliver research within the Portfolio, including dedicated clinical time for research and industry managers in each of the 15 LCRNs.

Training and support for research delivery staff, including Good Clinical Practice (GCP), is also provided by the CRN. Since the CRN began delivery, almost 100,000 individuals have completed the CRN GCP training.

Figure 4 maps these activities for both the commercial and non-commercial aspects of the clinical research market. For commercial studies, the relevant stakeholders include NHS Trusts and non-NHS sites who deliver the clinical research study as well as the sponsor companies who are funding the study and CROs which may be commissioned to manage the delivery of the studies. For non-commercial studies the relevant stakeholders are similarly NHS Trusts and non-NHS sites delivering the study, as well as the non-commercial sponsor of the study.
Figure 4: CRN study support for both commercial and non-commercial studies

Our report looks in more detail at a number of these activities and the impacts generated from them, with particular consideration of the role of the CRN in generating such impacts.
5 Economic impact of the CRN’s clinical research activity

This KPMG report estimates the gross value added77 and employment in the UK from CRN supported clinical research activity. We estimate that in the period April 2014 to March 2015 (FY 2014/15) this activity generated a total of £2.4 billion gross value added and almost 39,500 jobs.

In this section, we describe our approach to estimating the economic impact of clinical research supported by the CRN, drawing on the recognised economic impact analysis methodologies set out in HM Treasury’s Green Book.78 We then present our findings in terms of the total gross value added (GVA) and employment impacts generated by this activity.

5.1 A framework to estimate economic impact

The framework we have applied captures the contribution of CRN supported clinical research activity to the UK economy and more widely through a range of channels.

We first consider the economic contribution in terms of its GVA contribution including direct, indirect and induced impacts.

GVA measures the contribution to the economy of an individual producer, industry or sector, net of intermediate consumption (for example goods and services that are used in the production process).

It is a measure of the economic value of the services.79

The clinical research activity supported by the CRN directly adds GVA to the UK economy through the employment it generates within NHS Trusts80 and other care providers, universities, sponsor companies, CROs and within the CRN itself.

GVA at the industry or organisational level can be measured through two different approaches: the income approach and the production approach.81 We adopt the income approach which defines GVA as follows:

77 GVA is a measure of contribution to GDP. It is output minus intermediate consumption and shows the additional contribution to the economy of the industry. It is a key component of gross domestic product (GDP) which is a measure of the value of production and the state of the economy.
80 This report focuses predominantly on clinical research provided by secondary care providers, however we recognise these benefits are also realised for primary care providers who are also involved. With this in mind, hereafter, we will only refer to both primary and secondary care providers as NHS Trusts and other care providers.
\[ \text{GVA} = \text{Net pre} - \text{tax profit} + \text{Compensation of Employees} + \text{Depreciation} \]

We treat clinical research activity, both within the public sector, and within private sector R&D teams, as non-profit making. We, therefore, approximate the GVA impact by using data on payroll costs, representing the employee compensation element of GVA. The payroll costs associated with those involved directly in clinical research therefore represents the direct GVA impact.

Through this direct activity, there is also wider economic activity through the associated supply chains. For example, this could include suppliers of medical supplies or providers of management information systems in the case of NHS Trusts and care providers. Each of these suppliers also has their own suppliers, and so the economic activity perpetuates across the economy. This activity generated through supply chains is the indirect GVA generated by the CRN supported clinical research activity.

Induced GVA is also generated in the economy arising from additional economic activity generated by the direct and indirect employees spending a proportion of their wages in the UK economy. As part of our economic framework, we also consider these induced impacts.

We also consider the employment generated by the CRN supported clinical research activity.

Another measure of economic activity is the employment generated as a result of the clinical research being undertaken in the UK. Staff are employed by different stakeholders to set-up and run the clinical research activity within both the commercial and non-commercial arms of the Portfolio. This is the direct employment impact and is measured on a full time equivalent (FTE) basis.

Similar to indirect GVA contributions, the additional economic activity generated by the clinical research activity in the supply chain also results in additional domestic employment: indirect employment impacts.

Further ‘induced’ employment is generated by the additional economic activity resulting from the direct and indirect employees spending a proportion of their earnings.

We have estimated indirect and induced GVA and employment impacts using official multipliers.

We estimate indirect and induced GVA and employment impacts using sector specific GVA and employment multipliers sourced from the ONS\(^{82}\) and Scottish Government.\(^{83}\) The sector specific Type I and Type II GVA multipliers used in this calculation were sourced from the Scottish Government because the ONS does not produce Type II multipliers.


5.2 The impact by stakeholder type

A range of stakeholders are involved in clinical research supported by the CRN, through which GVA and employment impacts are generated. These stakeholder types are mapped out in Figure 5 below.

We also consider the level of their involvement across various study phases and as a result, where we would expect each to generate economic impacts in terms of commercial and non-commercial studies.

Figure 5: Categories of stakeholders involved in CRN supported clinical research

The economic framework to estimate the direct, indirect and induced impacts is consistent across all stakeholders.

However, the appropriate data sources and, therefore, the specific approaches, do vary. We distinguish these approaches as either top-down or bottom-up.

A top-down approach starts with high level data and makes relevant assumptions to capture the relevant activity we are estimating.
On the other hand, a bottom-up approach uses granular data at an individual level to scale up to capture the relevant activity to be estimated.

A description of each of these stakeholder groups, available data and our approach for each is detailed in Table 2. During the process of the study, we sought to gather data directly from all stakeholders to use a bottom-up approach. However, we faced a number of challenges in obtaining this data from CROs and sponsor companies which led us to adopt a top-down approach as the most robust approach based on the data available. Key learning from the data collection process feeds into the action plan detailed in Section 8.

Based on these estimates of direct GVA, we then applied sector specific ONS multipliers to estimate the indirect and induced impacts. Multipliers, as developed by the ONS, estimate the resultant impact on the supply chain and wider economy as a result of the direct GVA.

5.3 Limitations of our approach

The main limitation to this approach is data availability, in particular data regarding sponsor companies activities and non-commercial activity by universities or NHS Trusts.

Lack of data available from sponsor companies and CROs prevented a bottom-up approach – a preferred approach. In the absence of this, a top-down approach has been adopted which, as described above, is the most robust approach possible given the data available.

While we were able to obtain data from NHS Trusts to allow a bottom-up approach to be applied, in the timescales available to us it was only possible to collect data from a selection of NHS Trusts. These NHS Trusts were selected to ensure coverage geographically (both in London and outside of London) as well as a range of sizes and specialty expertise. However, the sample, and data collected, was also driven by which NHS Trusts would engage with us on the research and it therefore should not be considered a representative sample.

The analysis has been conducted for a single year only - FY 2014/15. This was due to data availability but prevents a year-on-year comparison. The Action Plan in Section 8 details recommendations to ensure analysis can be undertaken in future years to allow changes to be monitored over time.

The final limitation of this analysis is that it represents the gross rather than net impact of studies supported by the CRN. We provide a qualitative assessment of the additionality of the CRN in Section 7, but, given the lack of a clear counterfactual it has not been possible to quantify the extent to which this activity would be generated in the absence of its support.

The remainder of this section describes the estimation results. Further detail on the approach can be found in Appendix 1.

---


Table 2: Stakeholders, approach and source of data to estimate direct GVA

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Description of stakeholder type</th>
<th>Commercial</th>
<th>Non-commercial</th>
<th>Approach</th>
<th>Information sources for commercial</th>
<th>Information sources for non-commercial</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIHR CRN coordinating centre</td>
<td>Oversees the Portfolio, information management systems and recruitment metrics.</td>
<td>✓</td>
<td>✓</td>
<td>Bottom-up</td>
<td>NIHR CRN financial information.</td>
<td>NIHR CRN financial information.</td>
</tr>
<tr>
<td>NHS Trusts</td>
<td>NHS Trusts involved with clinical research either as a lead Trust / principle investigator or as a site.</td>
<td>✓</td>
<td>✓</td>
<td>Bottom-up</td>
<td>For NHS Trusts and other care providers, we use the same source of information to estimate. Based on the volume of patients seen to. We use the total staff costs on a per patient basis (collected as part of this study) to scale up.</td>
<td>For NHS Trusts and other care providers, we use the same source of information. Based on LCRN funding / infrastructure sourced from the NIHR CRN.</td>
</tr>
<tr>
<td>Other care providers</td>
<td>Other care providers, including primary care providers. They will be involved with clinical research as a site to recruit and deliver care to patients.</td>
<td>✓</td>
<td>✓</td>
<td>Bottom-up</td>
<td>The commercial activity undertaken at universities will be captured by the data used for NHS Trusts and other care providers. This data uses the costing template data, which will also capture the involvement of the universities.</td>
<td>The total grant funding as reported by UKCRC represents the research costs for universities.</td>
</tr>
<tr>
<td>Universities</td>
<td>All university involvement in clinical research activities – this includes work as principle investigator as well as investigator initiated trials for commercial studies.</td>
<td>✓</td>
<td>✓</td>
<td>Top-down</td>
<td>Top-down</td>
<td>Top-down</td>
</tr>
<tr>
<td>Contract Research Organisation (CROs)</td>
<td>CROs undertake clinical research activity on behalf of a client, usually sponsor companies. They can be involved with regulatory submissions, contract negotiations and set up activities on behalf of the Sponsor. They also deliver the studies.</td>
<td>✓</td>
<td>✓</td>
<td>Top-down</td>
<td>For sponsor companies and CROs, we use the same source of information. The ONS reports on the R&amp;D expenditure by pharmaceutical companies and CROs. We apply assumptions to these figures to estimate the level of expenditure on CRN supported clinical research for all sponsor companies and CROs.</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Sponsor companies</td>
<td>Includes pharmaceutical, biotech and medical device companies that commission studies. They will be involved in study set-up to negotiate contracts with sites as well as ongoing performance management. In some cases, they will also be involved in delivery of the studies.</td>
<td>✓</td>
<td>✓</td>
<td>Top-down</td>
<td>This data is sourced from the ONS Business Enterprise Research and Development.</td>
<td>Top-down</td>
</tr>
<tr>
<td>Charities / grant awarders</td>
<td>There are some staff involved in the allocation of grant awards to researchers. From our stakeholder engagement, charities usually have little involvement beyond the grant award phase.</td>
<td>✓</td>
<td>✓</td>
<td>N.a.</td>
<td>N.a.</td>
<td>N.a.</td>
</tr>
</tbody>
</table>


---

86 Health Research Analysis. 2014. 'The UK Health Research Analyses Datasets'. Available at: [http://www.hrcsonline.net/pages/data](http://www.hrcsonline.net/pages/data)
87 As defined by the NIHR CRN, non-commercial studies have allocated treatment costs (provisioned for by the NHS), study support costs (provisioned for by LCRN infrastructure and captured in the NHS Trusts stakeholder group) and research costs (which include all research costs that would not be incurred in the absence of the study, provided for by grant awards).
88 ONS data do not capture R&D expenditure by medical device companies. We scale up for this. The data also relates to all types of research (e.g. pre-clinical research and international roll out and line extensions) and we scale down to account for this. It also accounts for all CRN and non-CRN related clinical research, so we scale down to account for CRN supported studies only. All assumptions are based on information from the MHRA, the ABPI, our survey to sponsor companies and CROs launched as part of this study and clarified through stakeholder consultations.
90 Pharmaceutical companies will be involved in pharmaceutical-based studies. Medical device companies will be involved with device-focused studies.
91 There is no reliable data source that captures the staff involved in grant awards in charities in the UK. Disaggregating any data by CRN-specific studies would also not be possible. From our stakeholder engagement, the number of staff involved is likely to be small and have little impact on our overall estimate.
5.4 Results of our economic impact analysis

Our analysis estimates the economic impact for all commercial and non-commercial research activity supported by the CRN is £2.4 billion in GVA and almost 39,500 jobs in FY 2014/15.

This includes £778 million as a result of non-commercial activity, £1.6 billion due to commercial activity and £21 million due to the CRN Coordinating Centre’s activities. In the following sections we provide more detail on each of these strands of activity and their subsequent impact on the UK economy and employment.

5.4.1 The economic impact of non-commercial research activity supported by the CRN

For FY 2014/15, we estimate the total GVA impact of non-commercial clinical research activity supported by the CRN to be £778 million.

This GVA impact is made up of:

— £396 million attributed to activity within NHS Trusts and other care providers (using LCRN infrastructure); and
— £382 million due to the research activity undertaken at universities and by other principle researchers (supported by grant funding).

We estimate non-commercial clinical research activity supports 18,340 jobs in the UK.

— 11,593 of the employment created (in FTE) is attributed to activity within NHS Trusts and other care providers (using LCRN infrastructure); and
— 6,747 of the employment created (in FTE) is due to research activity undertaken at universities and by other principle researchers (supported by grant funding).

The breakdown of total GVA and employment by direct, indirect and induced impact is shown in Figure 6.
5.4.2 The economic impact of commercial research activity supported by the CRN

For FY 2014/15, we estimate the total economic impact of commercial clinical research activity supported by the CRN to be £1.6 billion.

This GVA impact is made up of:

— £137 million attributed to activity within NHS Trusts and other care providers; and
— £1.5 billion due to investment by sponsor companies and CROs.

We estimate the employment impact of commercial clinical research activity is 20,755 jobs in the UK economy.

— For NHS Trusts and other care providers, this is a 1,795 direct FTE employment impact, with an additional 225 FTE and 399 FTE due to indirect and induced impacts.
— For sponsor companies and CROs, this is 10,179 in direct FTE employment and 5,779 and 2,378 in indirect and induced employment impact (FTE).
The breakdown of total GVA and employment by direct, indirect and induced impact is shown in Figure 7.

**Figure 7: Economic impact of commercial clinical research activity supported by the CRN**

<table>
<thead>
<tr>
<th></th>
<th>NHS TRUSTS &amp; OTHER CARE PROVIDERS</th>
<th>SPONSOR COMPANIES &amp; CROS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total GVA:</strong></td>
<td>£137 million</td>
<td>£1.5 billion</td>
</tr>
<tr>
<td><strong>Direct GVA:</strong></td>
<td>£91 million</td>
<td>£711 million</td>
</tr>
<tr>
<td><strong>Indirect GVA:</strong></td>
<td>£16 million</td>
<td>£569 million</td>
</tr>
<tr>
<td><strong>Induced GVA:</strong></td>
<td>£30 million</td>
<td>£199 million</td>
</tr>
<tr>
<td><strong>FTE:</strong></td>
<td>2,419</td>
<td>18,336</td>
</tr>
<tr>
<td><strong>FTE:</strong></td>
<td>1,795</td>
<td>10,179</td>
</tr>
<tr>
<td><strong>FTE:</strong></td>
<td>225</td>
<td>5,779</td>
</tr>
<tr>
<td><strong>FTE:</strong></td>
<td>399</td>
<td>2,378</td>
</tr>
<tr>
<td><strong>Total Jobs:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Direct Jobs:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Indirect Jobs:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Induced Jobs:</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: KPMG analysis, 2016.

5.4.3 The economic impact of CRN Coordinating Centre activities

For FY 2014/15, we estimate the total economic impact of the CRN Coordinating Centre, including its supply chain and wider economic impacts, to be £21 million in total GVA and 283 in jobs – 170 directly employed and 113 due to indirect and induced impact.

The breakdown of total GVA and employment by direct, indirect and induced impact is shown in Figure 8.
Figure 8: Economic impact of CRN Coordinating Centre activities

<table>
<thead>
<tr>
<th>CRN COORDINATING CENTRE</th>
<th>£21 million</th>
<th>283 FTE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total GVA:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Direct GVA:</td>
<td>£11 million</td>
<td>170 FTE</td>
</tr>
<tr>
<td><strong>Direct Jobs:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indirect GVA:</td>
<td>£6 million</td>
<td>52 FTE</td>
</tr>
<tr>
<td><strong>Indirect Jobs:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Induced GVA:</td>
<td>£4 million</td>
<td>61 FTE</td>
</tr>
<tr>
<td><strong>Induced Jobs:</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6 Monetary benefits to NHS Trusts

In addition to the economic impact of clinical research activity, NHS benefits from additional revenues and cost savings.

We find that, for commercial studies, NHS Trusts receive an average of £6,658 in revenue, and a pharmaceutical cost saving of between £4,700 and £5,780, per patient recruited.

This equates to estimated totals of £176 million of commercial income and £16 million of pharmaceutical cost savings across the commercial CRN Portfolio for FY 2014/15.

This section considers two of these key benefits – payments to NHS Trusts for commercial studies and the cost saving to the NHS as a result of the pharmaceutical products provided free by sponsor companies.

6.1 Payments to NHS Trusts

Commercial clinical research is often commissioned by a sponsor company, or initiated by an investigator and then sponsored by industry. During the course of the study, the investigators and research sites receive payments from the sponsor companies and these payments represent a significant income stream, particularly for NHS Trusts.

Income to NHS Trusts from commercial studies cover the costs of staff time used in undertaking the study as well as, in some cases, indirect costs (such as overheads) and capacity building which is ring fenced to build sustainable research and innovation capacity. Secondary care providers (such as NHS Trusts) and primary care providers (such as GP practices) all benefit from income generated by commercial clinical research.

There is currently limited data held centrally by the CRN relating to the 'per patient payment' to NHS Trusts for commercial clinical research activity. To obtain this information we have therefore collected data directly from NHS Trusts to provide further insights into this value and how it varies by type of study.

6.1.1 A framework to estimate the per patient commercial payment

Previous work carried out by the CRN to generate estimates of the per patient payment found information to be incomplete and not easily accessible.

---

92 NIHR CRN Commercial Study Costing Templates. 2016. Available at: https://www.crn.nihr.ac.uk/can-help/life-sciences-industry/setup-service/

In some cases, Trusts do not use the commercial costing template. In these instances the pricing structure will different and they may not specifically price for indirect costs and capacity building. Instead these will be applied in a different way but will still be priced for.
An internal piece of work, undertaken in January 2016, looked to identify the average per patient payment relating to commercial studies. Commercial study costing templates were used as the source of collecting this information. This work identified that many study records held by the CRN did not include final costing templates. In cases where costing templates were available, the Business Analysts from the Business Development & Marketing Team within the CRNCC said it was difficult to find within the databases due to the quantity of files held for each study and inconsistency in the labelling of files.

Noting these challenges with CRN centrally held information, the approach we took involved reaching out to NHS Trusts directly to gather further information on:

— total budget estimated per patient; and
— on a per patient basis, the subtotal for both indirect costs and capacity building included in the total budget.

Although we recognise other bodies also deliver studies (for example, primary care providers such as GP surgeries), the focus for this piece of work focused on gathering information from NHS Trusts as this represents the majority of the Portfolio. In our Action Plan (see Section 8), we recommend further work to gather similar information from other care providers. We approached ten NHS Trusts as part of this report and received a sample of costing templates or aggregate data capturing the above variables from three NHS Trusts. These NHS Trusts vary in size in terms of their research capacity and are all located outside of London.

The above information was accessible for most NHS Trusts, however it was only held in aggregate form by 1. This meant for the other three NHS Trusts, this data had to be extracting from the costing templates manually for the purpose of this report. Recommendations to improve this if the CRN replicates this analysis going forward are detailed in Section 8.

Based on the information extracted against the above variables, we estimate the average per patient payment across all studies. We also consider how this varies by different types of studies, particularly by:

— the clinical specialty the study falls within;
— whether a study is interventional or observational in nature; and
— the phase of the study.

93 The commercial study costing templates provide a framework for transparent cost display and calculation to support swift local site budget negotiations when performing commercial trials in the NHS. This is provided by the CRN.
94 The CRN hold records on trials in the NIHR Coordinated System for gaining NHS permissions (CSP) database as well as the Central Portfolio management System (CPMS) database.
95 There are 30 different main clinical specialties that a study can fall into. A full list of these specialties can be found here: http://nuhrise.org/wp-content/uploads/NIHR-CRN-specialties-themes-and-operational-divisions-map.pdf
96 An interventional study is when participants are assigned to receive one or more interventions (or no intervention) so clinicians can evaluate the effects of that intervention.
97 An observational study is when individuals are observed, or certain outcomes are measured. No attempt is made to affect the outcome.
98 Most clinical research is divided into different stages, called phases. The earliest phases generally look at an interventions safety and the side effects it causes. Later phase studies generally test whether a new treatment is better than an existing treatment. The use of phases is not applicable for some observational studies.
6.1.2 Limitations of our approach

This analysis is based on data collected from a selection of NHS Trusts. As stated above, these NHS Trusts were selected to ensure geographical and specialty coverage however this should not be considered a representative sample.

Interpretation of how the per patient payments vary by specialty should also be interpreted with caution. The sample size (~400 studies) is split across 30 specialties. The smaller sample for individual specialties means that the average and median estimates are more vulnerable to the impact of outlier studies (for example, studies with extraordinarily high or low per patient payments).

It should also be noted that this analysis is based on the planned per patient payment information supplied by the NHS Trusts contained within the commercial costing template. This planned per patient payment should, in theory, be consistent with actual per patient payments, however there was insufficient data available as part of this research to assert this.

6.1.3 Per patient payments received by NHS Trusts and other care providers

Our estimates show the average per patient payment is estimated to be £6,658. This varies significantly, particularly by specialty type. Aggregated data across the commercial CRN Portfolio for FY 2014/15 suggests total commercial revenue to Trusts in the region of £176 million.

From the sample of costing templates and aggregate information obtained from NHS Trusts, we estimate the average per patient payment to be £6,658. Figure 9 illustrates the distribution of this average per patient payment, with the diagram showing the median value, of £5,000 per patient, the upper and lower quartiles and the extremes.

As can be seen, the distribution shows a downward skew, i.e. there is a concentration of results at the lower end of the range, indicated by the fact that the median value is below the mean. The mean value is pulled upwards by a small number of very high per patient payments and therefore is not as representative of the ‘typical’ study as the median value.

Figure 9: Average planned per patient payment, using sample collected for this report

Source: KPMG Analysis. 2016. We collected data from seven NHS Trusts for approximately 400 studies to estimate the above average planned per patient payment.
Higher per patient payments are noted for the following specialties: musculoskeletal disorders (£9,800 per patient, on average), cancer (£8,733 on average); neurological disorders (£8,500 on average) and hematology (£8,100 on average).

The per patient payment for interventional studies far exceeds that received for observational studies – on average £7,300 compared with £1,500. This reflects the greater need for staffing resources for interventional studies.

For FY 2014/15 we estimate total commercial revenue to NHS Trusts to be in the region of £176 million.

The total commercial revenue covers the costs directly associated with undertaking clinical studies, including direct staff costs and investigation costs, as well as a capacity building element, which is ring fenced to build research resources within NHS Trusts. This capacity building element represents a direct benefit to NHS Trusts of participating in commercial research.

The NIHR CRN commercial costing template states a 20 per cent capacity building element should be added to the study costings. This is not mandatory, and in some instances a higher value will be applied. However using 20 per cent as a lower limit, we estimate that at least £35 million of the total commercial revenue is allocated to capacity building.

6.2 NHS cost saving

As well as financial revenues to NHS Trusts generated from commercial studies, there are further financial benefits to the NHS in the form of cost savings through the provision of pharmaceutical products by sponsor companies for clinical research. Our report quantifies these cost savings and identifies how they vary across studies.

There are two routes through which the NHS may benefit from the provision of pharmaceutical products used as part of clinical research by sponsor companies.

1 Industry-sponsored clinical research studies testing pharmaceutical products provide NHS Trusts and patients with free access to these pharmaceuticals and treatments. This means the NHS Trust does not incur the cost of the standard treatment that the patient would have otherwise received (in the absence of the study). This represents a direct cost saving to the NHS.

2 Some industry-sponsored clinical research studies deliver value beyond this cost saving. Some studies provide NHS Trusts and patients with free access to more expensive pharmaceuticals that may be licensed in other indications, but are now being trialed in a new disease-area. In the absence of the study, patients would not have access to these more expensive and potentially effective pharmaceuticals. In this case, the value to the NHS stretches beyond the cost saving of standard treatment to the additional value of using these effective pharmaceuticals. This additional value will only be valid for some studies, and we consider what this additional value is using a case study.

It is important to note that although we focus on pharmaceutical cost saving and value for this report, there will also be similar savings generated by the use of medical devices. Data

---

99 NIHR CRN. 2016. ‘Set-up Services’, see industry costing template tab terminology. Available at: https://www.crn.nihr.ac.uk/can-help/life-sciences-industry/setup-service/
to quantify the cost of standard treatment using devices on a per patient basis is not available from public data and so this could not be quantified for this report.

6.2.1 **A framework to estimate the cost saving of the standard treatment**

In many studies, particularly in the case of randomised controlled trials (RCTs), there is ‘clinical equipoise’, meaning that there is substantial uncertainty about the expected efficacy of the pharmaceutical products being trialled. For most studies this means that, other than the revenues received by NHS Trusts, the main source of financial impact will be the cost saving in instances when NHS Trusts do not incur the cost of the standard treatment. It is this specific cost saving that we consider in this section of the report.

These cost savings are relevant for industry-sponsored or supported interventional studies using pharmaceutical products. Since 2010 a total of 2,059 interventional commercial pharmaceutical studies and 582 interventional industry-supported pharmaceutical studies have been entered onto the CRN Portfolio.

Not all commercial or industry-supported studies result in this type of cost saving – in some cases, the study drug may be used in conjunction with the standard treatment drug so the standard treatment cost is still incurred by the NHS. In other cases, there may be no drug used as part of the standard treatment so in this instance the use of the study drug does not represent any drug cost saving. For this analysis, we consider a cost saving to occur only when the use of the study treatment drug replaces the use of the standard treatment drug.

These three scenarios are mapped out in Figure 10 below. The scenario where cost savings to the NHS will be attributed is highlighted in red.

**Figure 10: Scenarios of cost saving to the NHS**


The approach to estimating the cost saving first considers which Scenario the study relates to, before using the study protocol to extract information on the name of the standard treatment drug, the maximum dosage and the duration of treatment. Zenrx, a pricing database for approved pharmaceutical products, is then used to extract information on the price for the standard treatment. We have done this for a sample across all specialties, as well as a deep dive into oncology.

6.2.2 **Limitations of our approach**

This approach considers the cost saving to the NHS due to the cost of the standard treatment pharmaceutical product only. It does not consider any other wider cost savings based on the trial treatment protocol.
The sample was randomly selected across the CRN Portfolio with information on standard treatment for these studies extracted from study protocols. It should be noted these protocol documents do not consistently record information on the treatment name (or dosage and duration of treatment). This means the sample, although randomly selected, is constructed based on those study protocols that had named the standard treatment pharmaceutical product.

A number of assumptions have also been applied regarding patient characteristics (for example, body weight) to estimate the standard treatment cost in some cases. These assumptions are based on population averages, but may differ from the actual patient characteristics, and therefore the actual treatment costs. Further details can be found in the technical annex.

As with the per patient payment data, interpretation of how the average cost saving varies by specialty should also be interpreted with caution. When split by the 30 specialties, the smaller sample size for individual specialties means there is the potential for extreme values to bias the average or median value.

6.2.3  The cost saving to the NHS

We estimate the total cost saving attributable to the CRN Portfolio is £16 million.

This is derived from an estimated average standard treatment pharmaceutical cost saving to the NHS within a range of £4,700-£5,780\(^{100}\) per patient across all specialties. For oncology studies, this saving is higher, in the range of £11,500-£14,000\(^{101}\) per patient.

The table below shows the total sample considered and how studies are distributed across the treatment scenarios identified. Roughly a third of cross-specialty studies sampled, and a quarter of oncology studies samples resulted in a cost saving.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Sample size considered</th>
<th>Scenario 1 – no standard treatment</th>
<th>Scenario 2 – standard treatment + study treatment</th>
<th>Scenario 3 – standard treatment instead of study treatment</th>
<th>No information available</th>
</tr>
</thead>
<tbody>
<tr>
<td>All specialties</td>
<td>155</td>
<td>10%</td>
<td>32%</td>
<td>35%</td>
<td>23%</td>
</tr>
<tr>
<td>Oncology</td>
<td>150</td>
<td>19%</td>
<td>45%</td>
<td>27%</td>
<td>9%</td>
</tr>
</tbody>
</table>

Source: KPMG analysis. 2016. Raw data extracted from study Protocols from the CSP database held by the CRN.

In general, oncology studies provide a more significant cost saving for NHS Trusts. There also exists more variation for oncology studies than for all specialties in general (see Figure 11).

---

\(^{100}\) This is an average of £5,250 + or – 10% (£4,700 to £5,780)

\(^{101}\) This is an average of £12,800 + or – 10% (£11,500 to £14,000).

\(^{102}\) See Scenario 3 as per Section 6.2.1.
Looking across the broad sample, the specialties with higher associated costs included neurological disorders and cardiovascular diseases. A full breakdown by specialty will not be robust because of the sample size – i.e. when we break the sample down to the 30 specialty areas, there is insufficient numbers of studies to ensure the estimate is robust.

The findings above for oncology studies are consistent with a UK-based study by Liniker et al (2013)\textsuperscript{103} that looked at the treatment costs associated with 27 studies in a single NHS Trust over a 2-year period. The study assessed patients who entered into oncology clinical studies involving investigational medicinal products in 2009 and 2010. Their treatment was analysed to identify the treatment costs versus the equivalent standard of care the patient would have received in the absence of the study. They found commercial studies represented an average cost saving of £9,294 per patient – an estimate slightly below the average found for our oncology deep-dive. These differences may be due to the variation in location (i.e. across multiple sites), variation in approaches taken by different investigators or inherent differences in the sample (i.e. different disease under study and treatment options).

A similar study in Taiwan found the saving per participant was in the region of US$3,900 per participant\textsuperscript{104}, equivalent to £2,410.\textsuperscript{105} This study similarly found oncology studies to be associated with higher cost savings.


\textsuperscript{105} This uses an exchange rate average for 2011 (the year of the study) of 0.61981 GBP to 1 USD.
Using the above estimates of the average cost saving to the NHS, we estimate that the cost saving attributable to the CRN Portfolio is £16 million.

We scaled up the cost saving based on the number of patients participating in pharmaceutical industry-supported studies. As we assume that only 35 per cent of these studies result in a cost saving to the NHS (i.e. Scenario 3), we apply this same proportion to the number of patients.\(^{106}\)

We then used the average cost saving per patient for all specialties (£5,250) to scale up to capture the cost saving for the whole Portfolio (it is estimated there are 11,780 patients who receive study treatments that represent a cost saving to the NHS).

**Box 4: Additional Value Beyond the Cost Saving to the NHS**

As well as the direct cost saving, there is also potential additional value generated by the use of the pharmaceutical products provided by industry as part of these studies. This may be because:

- patients are provided with access to effective pharmaceutical products that are licenced for other disease areas but being trialled in a new disease area;
- patients are provided with access to effective pharmaceutical products that are licenced in other countries, but being trialled in the UK for approval here;
- patients are provided with access to effective pharmaceutical products that are not yet licenced; or
- patients are provided with access to effective pharmaceutical products that are not currently standard treatment of care in the NHS.

It is important to note that this value will only be valid for some studies.

As part of this report, we have considered 8 oncology studies where it has been identified that one of the scenarios above applied. To quantify the value of the treatment pharmaceuticals to the patients we adopted the same approach as detailed in Section 6.2.1 but in this case applied to both the study treatment and the standard of care treatment. This involved:

- extracting information on the standard treatment pharmaceutical product from the study protocol, including details on the standard dosage and duration of treatment.
- extracting information on the study treatment pharmaceutical product from the study protocol, including details on the standard dosage and duration of treatment.
- cross-referencing the details of these products on the Zenrx database to extract information on their market value.

Bringing together the estimated market value of the study treatment and the standard treatment, on a per patient basis, we were able to estimate the additional value of access to the study treatment (the difference between these two estimates).

Across our limited sample we found the average additional value to be £57,735 per patient with a median value of £33,089. The additional value varies significantly however, from around £2,000 for one breast cancer treatment up to £234,822 for one prostate cancer study. While we cannot draw conclusions about the overall value generated by these types of studies, our sample does provide an indication of the substantial additional value to patients of access to more expensive treatments.

As patients become more research savvy, and are more aware of the study pharmaceutical products available, the ability to attract clinical research and be able to offer the preferred pharmaceutical products to patients becomes more and more important.

*Source: KPMG analysis.*

\(^{106}\) This relates to 11,781 patients.
7 Added value of the CRN

The impacts quantified in this report demonstrate the significant economic and financial value generated through clinical study activity supported by the CRN. We now consider the role of the CRN in supporting and enhancing this value, as well as the extent to which the activity of the network generates wider benefits to the clinical research market.

Additionality\(^{107}\) considers the net, rather than gross, impact after making allowances for what would have happened in the absence of Government support. As set out in HM Treasury’s\(^{108}\) Green Book, consideration of additionality is key to economic appraisals.

In this context, the additionality of the CRN within the clinical research market is not easily quantified. Capturing what the clinical research market would look like in the absence of the CRN support is not possible because of the multitude of factors impacting the UK clinical research market since 2011 (as discussed in Section 3). Stakeholders we spoke with also commented that it was not possible to make a judgement about the clinical research landscape in the absence of the CRN. We know that the number of studies on the CRN Portfolio has increased over time (as seen in Figure 12). However, the extent to which these studies would have been undertaken anyway, outside of the Portfolio, is very difficult to distil.

**Figure 12: Number of studies added to the Portfolio**

![Number of studies added to the Portfolio](source: NIHR CRN Study Summary data. Extracted March 2016.)

In the absence of a robust counterfactual against which to compare impact, our analysis of the added value of the CRN draws primarily on qualitative stakeholder consultation, combined with case studies providing specific examples of how the CRN generates value.

**We consulted 40 stakeholders, selected in collaboration with the CRN.**

The selection of stakeholders ensured we spoke with all relevant stakeholder groups, and achieved a mix of stakeholders within each. For NHS Trusts, we sought to speak to those

---

\(^{107}\) Additionality is the determination of whether an intervention has an impact when compared to a baseline or a ‘do nothing’ scenario.

located across the UK (inside London and outside of London) and with different levels of involvement in clinical research. For example, we sought to speak to NHS Trusts with a well-established clinical research reputation as well as those who are less established. For sponsor companies and CROs, we also tried to speak to those of ranging sizes and specialty focus. A full list of the stakeholders, their organisations and job titles are listed in 0.

Details of the consultation questions can also be found in Appendix 3.

In this section, we first provide a summary of the stakeholder responses. We then, based on the results of our stakeholder consultation, consider in more detail the added value of each of the CRN’s key services, particularly:

— the LCRN infrastructure;
— the CRN Coordinating Centre;
— study setup and site feasibility assistance; and
— model templates for commercial costing and agreements.

7.1 Summary of stakeholder responses

During stakeholder consultation, we identified the different routes to, and types of, impact attributable to the CRN.

Figure 13 summarises the routes to impact as identified by stakeholders during consultation.

Figure 13: The added value of the CRN as identified by stakeholders

![Diagram showing the added value of the CRN as identified by stakeholders](source: KPMG analysis. 2016.)

These impacts are broad and range from cost savings for NHS Trusts, to increased employment and growth opportunities to improved health outcomes for patients.
Stakeholders pointed out the interlinking and reinforcing nature of some of these benefits. They also reported that the extent to which these benefits are realised hinges on the volume of activity being undertaken.

On the volume of studies, there were mixed views regarding the role of the CRN. Among some stakeholders, particularly industry sponsors, there was a view that while the CRN provides a range of support to ease the process of setting up and running clinical studies, the volume of clinical research in the UK would remain broadly the same without the CRN. Some other industry sponsors, however, recognised it was difficult to disentangle what the landscape would look like without this established resource, meaning that this comparison is difficult to make.

An overall observation by all stakeholders was that the CRN has paved the way for a higher profile of the clinical research market in the UK. This was identified for both the international market for commercial research as well as within the UK and its funding landscape. It has also enabled more professionalism amongst Trusts, as highlighted by one Trust (quoted to the right). It was said that this had helped the NHS Trust increase its capacity to undertake studies, and income from studies.

“A number of positive wider spillovers, or externalities109, as a result of clinical research activity within NHS Trusts were also noted by stakeholders. These positive benefits are also noted in relevant academic literature. They include benefits to infrastructure, the learning and skill development of clinicians, as well as a quicker uptake of new treatments. This academic evidence of these impacts is presented below.

Improvements in infrastructure are recognised by Krzyzanowska et al. (2011)110 as a benefit of research. This report recognises that medical devices provided for by clinical research activity can have positive externalities for the non-study environment. This is particularly beneficial in resource-poor settings. Similar benefits were attributed to the acquisition of new skills for clinicians.111 A study by Europe Economics finds that participation in studies builds general human capital for physicians, enhancing their skills to the benefit of patients.112

Other studies have also found that countries which participate in clinical research are quicker to adopt new treatments – meaning patients are able to access new and effective treatments more quickly.113 This has been noted as particularly beneficial in oncology and cardiology.114

---

109 In economics, an externality is a consequence of the Government support that affects a party who did not choose to incur that cost or benefit. This can be positive or negative. In this case, an externality refers to benefits experienced that are not directly linked to the CRN supported trials, but are subsequent consequences because of its existence.


Another key benefit highlighted by stakeholders, in particular by NHS Trusts, is the improved quality of care and health outcomes for patients. There were benefits identified in terms of changing treatment pathways for patients, which could have cost savings for the NHS. It was argued that these benefits, although a by-product of the research, were furthered by the activity of the CRN. Some examples of these benefits can be seen in Case Study 1 below.

**CASE STUDY 1: DEVELOPING SECOND LINE TREATMENT FOR BLADDER CANCER**

This case study focuses on how support for one study can lead to additional industry interest in a particular research field. This additional interest can result in more studies, thus increasing the chance of improved treatment for patients and cost savings to the NHS.

Prior to 2012, there had been little research focused on bladder cancer in the UK. In 2012, a randomised phase 2 non-commercial study was added to the CRN Portfolio to investigate a study drug (pazopanib) in relapsed or progressive bladder cancer in comparison to standard treatment (weekly paclitaxel). The study recruited 131 patients. Although the study drug itself was not deemed successful, the study had two positive by-products which were important for bladder cancer research in the UK.

First, the study enabled the collection of the largest dataset on the control arm (which was standard treatment). This provided more robust insights to be gained into the effectiveness of the standard treatment.

Second the study proved that rapid recruitment onto bladder cancer studies was possible – a factor that attracted industry attention. The successful recruitment in this study led to further studies being commissioned by industry.

In particular, one industry-supported non-industry sponsored study was a randomised two-arm comparison study of a maintenance drug (lapatinib) versus placebo after first-line chemotherapy for patients with advanced or metastatic bladder cancer. 455 patients were recruited into the study, the results of which showed that maintenance therapy is possible for bladder cancer. A researcher for the study said the study allowed them to collect a large tissue biorepository which allowed biomarker testing – this involves looking at measurable indicators that indicate the severity or presence of some disease state.

Another study is testing a new agent (atezolizumab) which has already been licenced in the USA for second-line treatment. It is expected this will, in time, be standard care in the UK as well. Previously, no second-line treatment has been available for bladder cancer patients.

The researcher for the study said that while it was not possible to determine what the impacts of this particular treatment would be for the UK, the introduction of a second line treatment would be expected to reduce hospital admissions, improve survival rates, lower the use of primary and palliative care by these patients as well as reduce the use of palliative radiology. All of these have associated cost savings for the NHS.

**Source:** KPMG stakeholder engagement.

One sponsor company pointed to evidence that showed research-active organisations deliver health care that is associated with a higher quality of care. This was attributed to the standard processes implemented when undertaking research being, in general, of a higher standard (a by-product of the training that is required by clinical research undertakings).

All stakeholders also said the benefits of clinical research activity extend beyond those sites participating in research. This was because of the benefits related to the furthering of...
knowledge, development of new treatments and a subsequent change in treatment pathways (as seen in the Case Study 2 below).

**CASE STUDY 2: CHANGE IN TREATMENT PATHWAYS FOR PROSTATE CANCER**

*This non-commercial Portfolio study demonstrates how a clinical study can impact patient treatment. The study STAMPEDE was open in seven hospitals in Kent, Surrey and Sussex, recruiting 499 patients trialling a treatment for prostate cancer. The study has shown early treatment with a chemotherapy drug extends the lives of patients with advanced prostate cancer by nearly two years.*

The Portfolio study was launched in 2006, assessing the impact of a range of drugs and radiotherapy in conjunction with conventional hormone therapy. Almost 3,000 men with advanced prostate cancer took part in the study in Britain and Switzerland. Of these men, some were given six doses of the study drug in comparison to the standard treatment. On average, patients who received this drug lived ten months longer. For those in earlier stages of illness, the average increase in life expectancy was 22 months.

The evidence was identified by one of the researcher as showing that the treatment, usually used at more advanced stages of illness, has benefits when prescribed in the early stages of hormone therapy above the standard treatment. It was said this would also be a reasonably cheap prescribing pathway in comparison to the standard treatment, with the drug out of patent.


When asked what could be improved going forward stakeholders were keen to point out some of the activities they would like to see the CRN do more of, particularly clinical research awareness raising. They felt this was an area where the CRN had delivered particular value in the past and an area they were well placed to continue to do so.

Some stakeholders, particularly those in the local network and at NHS Trusts, felt that some of the commercial clinical research pipeline planning should be focused at a local level. Stakeholders felt locally engaged staff were better placed to make judgements on the feasibility and likely success of particularly research. With this in mind, they felt some of this planning and feasibility assessment would benefit from being undertaken more locally.

Sponsor companies and NHS Trusts in particular identified the valuable role the CRN had played in establishing relationships between the two sets of stakeholders and increasing participation in clinical research among NHS Trusts. However it was also noted that with these relationships now established, while there remains a role for the CRN in this space, the marginal returns will be lower, and therefore the CRN should consider how it can ensure that its value added in this space continues going forward. This could be, for example, through a greater focus on promoting engagement and collaboration across NHS Trusts.

In the following sections we explore how the CRN has delivered such value, focusing on the LCRN infrastructure, the activities of the CRN Coordinating Centre, study setup and site feasibility services as well as model templates.

### 7.2 LCRN infrastructure

*Stakeholders, particularly those in NHS Trusts, considered the CRN infrastructure to be integral to delivery of clinical research, particularly for non-commercial studies.*

This infrastructure provided by the LCRN was cited as a substantial resource by all stakeholders. A representative from a charity said that the LCRN infrastructure was critical for the non-commercial landscape.
The support provided for recruitment was particularly noted by a number of stakeholders. It was stated by a sponsor company that developing a track record for on target recruitment was essential to continue to attract investment. A researcher also noted that this was important to develop commercial interest in relation to some specialty areas. For example, bladder cancer had received little commercial attention until a study proved that patients, fit for similar studies, could be rapidly recruited in the UK. The researcher said this paved the way for future research in bladder cancer enabling patients to participate.

While some stakeholders reported that funding could potentially be found from elsewhere, be that from commercial or grant funding sources, this would be difficult. There was also a view that the mix of studies, in terms of commercial and non-commercial may potentially change, with commercial studies being attractive because of their income stream. A charity representative said the loss of this funding stream would be very detrimental to its portfolio of studies and for the research agenda for the UK as a whole. They said the knock on impacts would be severe.

“We couldn’t fund the gap that would be left by the CRN resources. We would have to have a different strategy and take on other [commercial] research.”

NHS Trust

One NHS Trust said the LCRN infrastructure also helped establish a presence for commercial studies, assuring sponsor companies there was a ready-to-go in-house service for clinical studies with the required skill set and training. This means sponsor companies can be assured there are clinician staff with the necessary GCP training and with information management processes in place to effectively manage a study.

Further, the ability to deploy LCRN resources, based on where research demands are, was cited as an advantage by NHS Trusts. This is particularly highlighted in Case Study 3 below.

CASE STUDY 3: FLEXIBLE WORKING

The North Thames LCRN has a central team, funded by the Network, with flexible working patterns dedicated to the non-malignant haematology specialty area. Staff have been appointed in two main hubs and employed specifically to work in a hub and across other Partner Organisations as the Portfolio in this specialty develops.

By enabling capacity and resources to be moved around the Network in response to needs and demand, this approach has generated process efficiencies and enabled partners to establish new studies quickly.

Resources can be deployed depending on the differing needs of Partner Organisations. This has also meant patients are able to access haematology studies at sites where activity was not previously available. Patient recruitment has also increased significantly from the previous year (by 60 per cent).

The possibility to develop these teams in different specialty areas is also being explored.

Source: LCRN North Thames Annual Report 2014-15

The staff involved with CRN clinical research benefit from training and development offered by the CRN. This was reported as valuable by all stakeholders and has a sizeable cost saving element for NHS Trusts and other care providers.
The CRN provides a range of training that is made available to NHS Trusts and clinicians. In particular, they provide for the Good Clinical Practice (GCP) training – a legal requirement by the Health Research Authority (HRA).116

Prior to the CRN providing this GCP training, the equivalent training was provided by NHS Trusts on an ad hoc basis, commissioned from external training providers. For commercial studies, sponsor companies would, in some cases, require clinicians to undertake their own bespoke training to ensure the quality and competency of staff. Often, this meant staff were completing similar training multiple times if working with multiple sponsor companies.

Since the CRN has been in existence, clinicians can access GCP training (either face-to-face or online) and this is widely accepted by sponsor companies117 and the MHRA. The creation of TransCelerate in 2012 also has enabled the members (sponsor companies) to develop a mutual recognition program where the GCP training is accepted by all.

CASE STUDY 4: GOOD CLINICAL PRACTICE TRAINING

All clinicians who undertake clinical research are required to complete Good Clinical Practice (GCP) training. It ensures the rights, safety and wellbeing of research participants are protected and that research data is reliable.118 This is now provided by the CRN. In the last financial year, over 30,000 staff benefited from CRN-supported GCP training. This represents a significant cost saving for NHS Trusts.

It is mandatory for all clinicians and staff working on clinical studies to undertake GCP training, as required by HRA. The CRN now provide for this training and it has been undertaken by over 30,000 staff in the last year. Modes of training include face-to-face sessions as well as e-learning which has improved access.

Prior to the CRN providing GCP training, the training was undertaken by individual NHS Trusts. NHS Trusts would usually hire external training providers, therefore incurring an upfront cost of training, as well as ongoing costs associated with maintenance of GCP to keep knowledge current.

There were also previous issues with duplication of GCP training by different sponsor companies. For example, two different sponsor companies would require their own GCP training to be completed meaning clinicians would spend double the time on completing these qualifications. A back of the envelope estimate as part of this report shows this would cost, in time, seven hours of a clinician’s time if delivered face-to-face.

Since the CRN began providing GCP training it has increased its reach– GCP training reached roughly 3,000 people in 2006, rising to 30,000 in 2015. A recent spike has been linked to the introduction of e-learning which has improved accessibility. The growth in the number of staff completing the CRN GCP training is shown to the left.

The main advantages of the GCP training provided by the CRN is established to be:

- Consistency on the GCP training across NHS Trusts and individuals. The same standards are now applied for all clinicians by a centralised body. This means no discrepancies between NHS Trusts;
- Clinicians are not required to undertake multiple GCP trainings with the accreditation provided by the CRN accepted by all stakeholders (sponsor companies, MHRA and others);

116 The HRA require for all researchers involved with investigational medicinal products to undertake Good Clinical Practice training.

117 TransCelerate is a consortium of pharmaceutical companies. It agrees that the CRN GCP training meets its requirements and it is recognised by all members. This avoids duplication of training for different sponsor companies. The CRN is not involved but TransCelerate benefit from the GCP training provided by the CRN.

118 NIHR CRN. 2016. 'Good Clinical Practice (GCP) training'. Available at: https://www.crn.nihr.ac.uk/learning-development/good-clinical-practice/
CASE STUDY 4: GOOD CLINICAL PRACTICE TRAINING

- A common accepted standard by sponsor companies, with this formalised through TransCelerate; and

- It is easier for the GCP to anticipate regulatory changes and disseminate this information to the UK. Previously any changes would have to have been adopted by each individual NHS Trust, with resources required to update the GCP training and the knowledge of clinicians. Now, the CRN can engage with regulatory bodies early and disseminate any necessary knowledge or changes to its network.

“We have huge reach in being able to update the whole research community quickly if a change needs to be communicated quickly.”

Source: KPMG stakeholder engagement

7.3 CRN Coordinating Centre

Positive network effects are cited by stakeholders in relation to the activities of the CRN Coordinating Centre. This refers to the effect that a single user of a service has on the value of that service to other people.\(^{119}\) The increasing participation in the network by stakeholders, such as NHS Trusts, sponsor companies and CROs, has direct benefits for stakeholders already involved.

For example, the NHS Trusts benefit from a greater number of sponsor companies opting to use the CRN to connect with potential sites. The greater the number of sponsor companies using the CRN, the more the opportunities to respond to requests for interest and become a site for a study. In turn, this gives them access to equipment, pharmaceutical products and funding. For sponsor companies, this means they will identify the most appropriate site and patient pool for the study.

The connections in the network are also important because it increases access to information and helps prevent duplication of effort. For example, for a sponsor company when identifying sites for a study, it can identify interest and appropriateness through engagement with the CRN rather than individually at each individual site level.

Other significant benefits, particularly regarding sharing of best practice and the use of specialty, leads in enhancing collaboration is noted as a significant added-value.

One NHS Trust said there is a tendency for Trusts to act in silos due to the perceived competition between them. However, in reality, NHS Trusts needed to support the research activity of other NHS Trusts because of the patient population or specialty knowledge. Such collaboration is inherently difficult, and the added value of the CRN is that it enables this sharing.

“Sometimes, research conducted in certain sites had inconsistent approaches The CRN now provides that consistency.”

Representative from a charity.

The setup of the different specialty groups was often cited as a means for this sharing to take place. One representative from a charity said this collaboration was a distinct advantage in the UK.

Some other stakeholders, particularly from outside NHS Trusts, noted this had also benefited the consistency of approaches across Trusts.

---

meant that processes were consistent, infrastructure and capability was consistent and they were able to access support if needed.

The independence of the Coordinating Centre in monitoring performance and allocating funding is also a benefit for the clinical research market.

Some stakeholders we spoke with, who had worked in clinical research prior to the CRN being established, noted the independence of the Coordinating Centre in performance management and allocating funds based on performance was a distinct advantage.

The role of the Coordinating Centre allows the bigger picture to be taken that circumvents local politics and manipulation of any performance metrics. This strategic oversight was seen as a real added value within the market.

The growing pool of participants in the network has increased the profile of the commercial clinical study market, a consequence of the Coordinating Centre’s efforts.

“The network has tangibly increased our commercial trial activity and performance. If the network wasn’t here, we’d be struggling to attract and delivery for industry.”
NHS Trust.

Some stakeholders said the Coordinating Centre had tangibly increased the level of commercial research activity. It was indicated that, without the support and activities of the Coordinating Centre, it would not be able to attract these studies in the first instance. This was noted by smaller NHS Trusts which have less of a historic role in clinical research.

The role the Coordinating Centre also plays with monitoring performance was noted as important here.

7.4 Study setup and site feasibility

A number of stakeholders said the study set-up process, and the time this takes, has benefited from the CRN’s ability to help with site feasibility. The CRN’s focus on study setup time as a metric is also very useful to ensure a quick process.

One of the high level objectives of the CRN is to ensure the time taken to get NHS permission for a study to start is reduced (to within 40 calendar days from receipt of a valid complete application to the CRN). Stakeholders indicated that the use of the metrics to monitor the achievement against this objective was helpful to ensure resources are focused to meet this. Recent performance results show that 79 per cent of eligible studies are obtaining these permissions within 40 calendar days.

Benefits were also noted in terms of getting the support to start recruitment quickly.

The ability of the CRN to support the study set-up process, including linking up sites and assisting with training around GCP and the protocols, meant studies could start recruitment quickly. This point was raised by sponsor companies, one charity we spoke to and was also reiterated by CRN staff. The sponsor companies were keen to point out that the pace with which recruitment could start was one of the main drivers of location decisions.

Sponsor companies also pointed out the CRN enabled them to identify sites that it would otherwise not have reached out to.

These benefits were particularly prevalent for international sponsor companies that have little experience in the UK clinical research market (see Case Study 5 below). For those more established in the UK market, existing relationships with NHS Trusts and researchers are most often used.

Some sponsor companies identified the site feasibility to be particularly useful for identifying specialty experts (i.e. NHS Trusts or researchers with an expertise in a particular specialty area). The CRN helps to link them up with these experts and provide site information regarding performance to time and target.

**CASE STUDY 5: NOVIAN HEALTH**

Novian Health, a Chicago-based medical device company, has a single product which it is trying to get to market. It has worked with the CRN to implement a Phase 2 multinational study, having no prior experience in the UK market. Using the CRN, Novian Health has successfully linked up with sites and lead researchers and the study has exceeded recruitment targets. This has been such a success it is now looking at further studies to be based in the UK.

In 2013, Novian Health had MHRA approval for a Phase 2 study, with an established relationship with a lead London-based investigator. Due to unforeseen circumstances, the lead investigator was unable to continue with the study and Novian Health were left to navigate the UK clinical research landscape and identify appropriate sites and researchers to run its study.

With no prior experience in the UK, Novian Health reached out to the CRN. The CRN helped to facilitate requests of interest to be sent out. A number of sites responded to this request, with three sites chosen in Bristol, Norwich and Chelmsford.

Novian Health said the process for study set-up and approval was straightforward. It was felt the ease with which request for interest could be sent out to all potential sites as a real competitive advantage to other European countries. Novian Health also said, once it had Portfolio approval, it was impressed with the speed that expressions of interest happened – it said within 30 days it had expressions of interest and was able to make a decision on the sites and proceed to study-set up very quickly after this.

One key enabling factor for study set-up was the use of model templates. It was felt the costing template meant there was little need to negotiate beyond simple queries and questions. The contractual template was also cited as being straightforward and useful.
### CASE STUDY 5: NOVIAN HEALTH

“**In our view, you’re dealing with an agency that is in sync with industry [...] it gets the sites performing at quicker rates than we experience elsewhere.**”

Ongoing monitoring by the CRN and the use of metrics was also highlighted as another benefit. Novian Health said the metrics used by the CRN to track enrolment matches what it uses internally. It felt this was helpful and improved accountability of the sites.

Almost half of the population was provided by the UK sites, despite it having only a quarter of the sites. Novian Health said this was a real competitive advantage of the UK – the ability to tap into a significant volume of patients via the NHS. This, paired with the intelligence provided by the CRN regarding any studies that may be competing for the same patient population, meant it is very appealing to sponsor companies.

In total, the study had a target population of 60 patients across 12 participating sites – three in the UK and nine in the US. In total, Novian Health said this was a real competitive advantage of the UK – the ability to tap into a significant volume of patients via the NHS. This, paired with the intelligence provided by the CRN regarding any studies that may be competing for the same patient population, meant it is very appealing to sponsor companies.

In total, the study had a target population of 60 patients across 12 participating sites – three in the UK and nine in the US. Novian Health said this was a real competitive advantage of the UK – the ability to tap into a significant volume of patients via the NHS. This, paired with the intelligence provided by the CRN regarding any studies that may be competing for the same patient population, meant it is very appealing to sponsor companies.

Overall, Novian Health said the entire process was straightforward. The study was a success – it was run efficiently, it over-recruited and the costs were comparable to other markets. It is launching another study in the coming year, and its experience with the CRN has encouraged the company to place six sites in the UK for the next study. It is hoping to attract more interest from other sites.

**Source:** KPMG stakeholder engagement

---

#### 7.5 Model templates

_The use of the costing template and model agreements have had process efficiencies for some stakeholders and had positive impacts on the market in terms of pricing._

NHS Trusts, sponsor companies and CROs all identified the existence of process efficiencies resulting from the provision of model templates, such as the commercial costing templates. Sponsor companies said this has had a positive impact on the time taken to negotiate costings and contracts for new studies meaning it is able to get studies ‘up and running’ more quickly. This time-saving element has a direct impact for NHS Trusts, allowing this time to be freed up and allocated to the set up and delivery of additional studies, thus increasing the overall clinical research capacity.

An additional benefit identified as resulting from the provision of standardised costing templates by the CRN is the transparency this enabled. A number of sponsor companies identified that this transparency meant there was greater consistency in pricing across the UK. This enables higher-priced sites to be identified and the negotiation process to be more structured.

**“We have open and transparent rates that are agreed through the costing template. If the CRN stopped existing, the template would cease to exist, and I think a cost inflation would then result.”**

Sponsor company

The process efficiencies and transparency gains were reported to be particularly noticeable for smaller NHS Trusts and those not as accustomed to clinical research. Some other NHS Trusts we spoke to choose to use their own bespoke costing tools. One larger NHS Trust in particular said it chose to use its own templates because of its previous experience with clinical research and the volume of commercial studies it has undertaken. Because of its already established practices, these efficiency gains were not applicable.
8 Action plan

This action plan summarises the lessons learned from data collection as part of this report, and recommendations on what data should be captured going forward and how, for ongoing monitoring and evaluation purposes.

We understand that the CRN wants to carry out ongoing monitoring and evaluation to measure the impact and value of its activity.

This section provides a proposed action plan setting out what data are needed for this purpose and how they can best be captured, taking into account the data availability and resource limitations we have identified as part of this report.

For several data sources used in this report data extraction has been a resource intensive process. This is because the required data were not recorded or reported in a systematic way. As part of the action plan, we, therefore, consider steps that could be taken to enable these metrics to be more easily collected and the relative resource requirement of each on the stakeholders involved.

We set out in the following sections our key learning from this report and recommended actions that could be taken to improve the data collection process for the three elements of impact considered: economic impact analysis, per patient payment and pharmaceutical cost savings.

The full methodology setting out the approach to the analysis used in this report, and which can be used for ongoing monitoring and evaluation, is set out in Appendix 1.

8.1 Recommendations for economic impact analysis

<table>
<thead>
<tr>
<th>KEY LEARNING: IN SUMMARY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsor companies and CROs:</td>
</tr>
<tr>
<td>Sponsor companies and CROs are unable to provide employment and R&amp;D data related only to CRN related activities, or disaggregated only to the UK. There are also some challenges with commercial sensitivities. We therefore use a top-down approach to estimate their economic impact, using ONS data. However, more evidence on the appropriate assumptions to apply to this is needed.</td>
</tr>
<tr>
<td>NHS Trusts:</td>
</tr>
<tr>
<td>The way NHS Trusts hold payroll cost and employment data does not allow for disaggregation by CRN-related clinical research activity only. An alternative bottom-up approach, using information extracted from the commercial costing template, is used to scale up for the Portfolio (based on actual recruitment numbers). However, access to and extraction of this data has been resource intensive.</td>
</tr>
<tr>
<td>LCRN</td>
</tr>
<tr>
<td>Data is comprehensive to estimate the impact as a result of the LCRN infrastructure. Some further work to understand how much double-counting is present for LCRN employment is needed to ensure robustness.</td>
</tr>
<tr>
<td>CRN Coordinating Centre:</td>
</tr>
<tr>
<td>NIHR CRN data is comprehensive and is fit-for-purpose to estimate the economic impact.</td>
</tr>
</tbody>
</table>

In light of the challenges associated with data availability and data collection that we have identified as part of this report, we set out below a number of recommendations relating to
the economic impact analysis. We recognise these recommendations will generate some additional burden for stakeholders. In Figure 14, we present our recommended actions along with an indicator of the burden of implementation for the relevant stakeholders.

Further detail on the metrics, data challenges and recommendations going forward can be found in Table 4 of the annex to this Action Plan.

**Figure 14: Action plan for economic impact analysis**

**ACTION PLAN GOING FORWARD – SPONSOR COMPANIES / CROS**

- **E.1**: Undertake an annual survey for sponsor companies / CROs to capture reliable information to apply to the ONS data.
  - The survey would aim to capture reliable data regarding the value of medical device companies’ R&D expenditure, the proportion of UK R&D expenditure spent on clinical research activity and the proportion of this relating to the CRN Portfolio.

**ACTION PLAN GOING FORWARD – NHS TRUSTS & UNIVERSITIES**

- **E.2**: Require sites to provide per patient information to the CRN in an aggregate form.
  - Compulsory submission of per patient costs and staffing hours per patient – this would be based on agreed group costing template. This could also include submission of actual costs based on what has been invoiced and patient recruitment.

- **E.3**: Require comprehensive grant income information and how much is spent on staff from principle investigator.
  - As part of the application to the CRN, investigators should be required to disclose amount of grant income received and how much will be spent on staffing.

**ACTION PLAN GOING FORWARD – CRN**

- **E.4**: Record more granular detail on LCRN FTE resources.
  - A requirement for more granular detail on LCRN FTE resources (using consistent IDs for individuals) and how this is deployed. This will minimise double counting and enable greater granularity regarding how LCRN resources are used.

**Note**: This excludes any action plan relating to improving the per patient payment information.
8.2 Recommendations for average per patient payments

KEY LEARNING: IN SUMMARY

The collection of data within the commercial costing templates was a challenging and resource-intensive exercise. Although information on planned per patient payments is held by NHS Trusts, this is usually not in an aggregate form. It is usually held in the commercial costing template and is resource-intensive to extract.

There are also some commercial sensitivities for NHS Trusts when sharing information from the site specific commercial costing templates and in some cases non-disclosure agreements are in place meaning that approval from sponsor companies would need to be gained before disclosing un-anonymised templates. It is unlikely it would be feasible to obtain final costing agreements at each site, however agreed costings at a group level may be possible.

Planned per patient payments (based on the costing template) and realised per patient payments (that NHS Trusts actually invoice for) can differ. It is likely this may be due to invoicing delays or schedules however little data is currently available to consider this.

Based on our report, we have made the following recommendations for the collection of information on per patient payments going forward. Our recommended actions, and the indicative burden for stakeholders, are presented in Figure 15. Further detail on the metrics and associated data challenges relating to per patient payments is provided in Table 5 in the annex to this Action Plan.

Figure 15: Action plan for per patient payments

ACTION PLAN GOING FORWARD

P.1: Require compulsory submission of finalised commercial costing templates.
NHS Trusts would be required to ensure the final agreed group commercial costing template is available via the CPMS. Relevant information could then be extracted by the CRN.

P.2: Require NHS Trusts to submit per patient payment information to the CRN in an aggregate-form.
NHS Trusts would be required to aggregate data on per patient payment, based on the commercial costing template. They would also be required to do a similar aggregation with invoice information per study.
8.3  Action plan to estimate the average cost saving to the NHS

KEY LEARNING: IN SUMMARY

Information in the study protocols is not captured in a systematic way. This has the following implications:
- It is not easy to identify whether a study results in a cost saving to the NHS from the study protocols.
- Information on the standard treatment is also not easy to identify, with no specific field in the protocol requiring information on this. In some cases, this information is not available at all.
- This meant the process of data collection was resource-intensive and required a comprehensive review of the protocols to identify the relevant information.

It is understood the CRN cannot influence the content of the study protocols. It is suggested that this information can be submitted separately as part of the application for CRN Portfolio eligibility.

Our recommendations relating to analysis of the average pharmaceutical cost saving are detailed in Figure 16. Here we consider the associated burden for stakeholders, in particular lead researchers. Further detail on a metric-by-metric basis can be found in Table 7 within the annex to the Action Plan.

Figure 16: Action plan for estimating cost saving to the NHS

**ACTION PLAN GOING FORWARD**

<table>
<thead>
<tr>
<th>Low burden for researchers</th>
<th>Medium burden for CRN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>D.1:</strong> Require submission of standard treatment information as part of the CRN Portfolio eligibility application.</td>
<td></td>
</tr>
<tr>
<td>This would require Principle Investigators to report, in an appropriate form as part of eligibility application, what standard treatment would be applied, and whether the trial treatment replaces this.</td>
<td></td>
</tr>
</tbody>
</table>

**OR**

<table>
<thead>
<tr>
<th>High burden for researchers</th>
<th>Low burden for CRN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>D.2:</strong> Require NHS Trusts to estimate the cost of standard treatment on a per patient basis.</td>
<td></td>
</tr>
<tr>
<td>This option goes further than Option 1, requiring NHS Trusts to estimate the cost of the standard treatment, on average, per patient. This would be based on the protocol and standard of care related to the standard treatment.</td>
<td></td>
</tr>
<tr>
<td>A non-quantifiable impact assessment could also be appropriate.</td>
<td></td>
</tr>
</tbody>
</table>
### 8.4 Annex to the Action Plan

**Table 4: Metrics to undertake economic impact analysis**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Description</th>
<th>Challenges with data collection</th>
<th>Our approach to data collection</th>
<th>Source of data</th>
<th>Recommendations going forward</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TO ESTIMATE GROSS VALUE ADDED</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Payroll costs for sponsor companies and CROs</td>
<td>The payroll costs of staff working on CRN clinical research studies for all sponsor companies and CROs.</td>
<td>Global sponsor companies and CROs are often unable to provide data that relates only to the UK (and CRN specific studies). We also identified hesitations in providing data because of commercial sensitivities.</td>
<td>This data has only been obtainable top-down, based on ONS BERD data covering the sector as a whole. Assumptions have been applied to adjust the data: (a) to cover only clinical research activity; (b) to include the activity of medical device companies; and (c) to cover only CRN supported studies.</td>
<td>ONS (with assumptions applied)</td>
<td>E.1.1. CRN to undertake an annual survey to capture reliable information on assumptions to apply to ONS data. E.1.2. CRN to undertake an annual survey for key sponsor companies to capture U clinical research payroll costs.</td>
</tr>
<tr>
<td>Payroll costs for NHS Trusts and universities for commercial activity</td>
<td>The payroll costs of staff working on CRN clinical research studies (commercial or industry-supported) stationed at NHS Trusts and/or universities.</td>
<td>For NHS Trusts, data is often held in an aggregated form across operations and cannot be easily broken down to CRN-related clinical research activity. For universities, this data is similarly not held in a way that allows easy extraction of CRN related clinical research activity.</td>
<td>We have used a bottom-up approach, based on the total staff costs per patient within the CRN Portfolio (the associated payroll costs of staff). We have then used total actual patient volume to scale up.</td>
<td>Commercial costing templates</td>
<td>Recommendations to improve data collection regarding planned per patient payment covered in Table 5. E.2. NHS Trusts / universities to provide actual (rather than planned) per patient payment information, related to staffing costs, to the CRN.</td>
</tr>
<tr>
<td>Payroll costs for NHS Trusts and universities for non-commercial activity</td>
<td>The payroll costs of staff working on CRN clinical research studies (non-commercial) stationed at NHS Trusts and/or universities.</td>
<td>For both NHS Trusts and universities, the data is held broadly across operations and cannot be easily broken down to CRN-related clinical research activity.</td>
<td>We have used a top down approach, using overall grant funding for the sector as a whole. Assumptions have been applied to adjust the data: (a) to cover only clinical research, and (b) to cover only CRN supported studies.</td>
<td>UK Clinical Research Collaboration</td>
<td>E.3. CRN to require more comprehensive submission of grant income relevant to study applications.</td>
</tr>
<tr>
<td>Payroll costs for LCRN staff</td>
<td>The payroll costs of LCRN study support staff working on CRN clinical research studies (non-commercial) and stationed at NHS Trusts.</td>
<td>None. Data provided by the LCRN regarding payroll costs is comprehensive.</td>
<td>We have used total payroll costs of LCRN study support staff.</td>
<td>NIHR CRN</td>
<td>-</td>
</tr>
<tr>
<td>Metric</td>
<td>Description</td>
<td>Challenges with data collection</td>
<td>Our approach to data collection</td>
<td>Source of data</td>
<td>Recommendations going forward</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>Payroll costs for NIHR CRN Coordinating Centre</td>
<td>The payroll costs of staff working in the NIHR CRN Coordinating Centre.</td>
<td>None. Data provided by the CRN regarding payroll costs is comprehensive.</td>
<td>We have used total payroll costs of CRN Coordinating Centre staff.</td>
<td>NIHR CRN</td>
<td>-</td>
</tr>
<tr>
<td>Number of patients recruited to commercial studies in relevant year</td>
<td>The number of actual patients recruited for the relevant year of interest is needed to scale up the impact for NHS Trusts and universities undertaking commercial activity. This is done by multiplying the payroll cost per patient (using the commercial costing template as above).</td>
<td>None. Data available at a site level for commercial studies via the ODP database.</td>
<td>We have extracted the relevant data from the ODP database.</td>
<td>ODP database</td>
<td>-</td>
</tr>
<tr>
<td>TO ESTIMATE EMPLOYMENT IMPACT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employment by sponsor companies and CROs</td>
<td>The number of FTE staff employed by sponsor companies and CROs working on CRN clinical research activity.</td>
<td>Similar to payroll costs, global sponsor companies and CROs are often unable to provide data that relates only to the UK (and CRN specific studies). We also identified hesitations in providing data due to commercial sensitivities.</td>
<td>We used ONS BERD data which provides the total FTE employment associated with pharmaceutical R&amp;D. We applied the same assumptions as for ONS BERD payroll costs to arrive at our final FTE estimate.</td>
<td>ONS with assumptions</td>
<td>E.1.1. CRN to undertake an annual survey to capture reliable information on assumptions applied. E.1.2. CRN to undertake an annual survey for key sponsor companies to capture UK clinical research FTE.</td>
</tr>
<tr>
<td>Employment by NHS Trusts and universities for commercial activity</td>
<td>The number of FTE staff employed by NHS Trusts / universities for commercial activity.</td>
<td>As above, data is held in aggregate from and cannot be broken down to provide CRN-specific clinical research activity.</td>
<td>We have used a bottom-up approach, based on the total GVA estimate (as above) and dividing by the average GVA per employee for the sector. This provides us with an estimate of FTE employment.</td>
<td>Commercial costing templates</td>
<td>E2. NHS Trusts / universities to provide actual staffing hours per patient.</td>
</tr>
<tr>
<td>Employment by NHS Trusts and universities for non-commercial activity</td>
<td>The number of FTE staff employed by NHS Trusts / universities for non-commercial activity.</td>
<td>As above. Staff are also often funded through a number of different streams of income which makes identifying relevant staff complex.</td>
<td>We have used a top down approach, using overall grant funding for the sector as a whole. As above, assumptions have been applied to adjust the data to include only CRN supported clinical research.</td>
<td>UK Clinical Research Collaboration</td>
<td>E3. CRN to require more comprehensive submission of grant income relevant to study applications.</td>
</tr>
<tr>
<td>Employment by LCRN</td>
<td>The number of FTE staff employed by LCRN.</td>
<td>Data provided by the LCRN is comprehensive. However, it was</td>
<td>We have used FTE data provided by the LCRN.</td>
<td>NIHR CRN</td>
<td>E4. LCRN to provide more accurate records on LCRN FTE resources (ensuring</td>
</tr>
<tr>
<td>Metric</td>
<td>Description</td>
<td>Challenges with data collection</td>
<td>Our approach to data collection</td>
<td>Source of data</td>
<td>Recommendations going forward</td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------</td>
<td>------------------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>Employment by NIHR CRN Coordinating Centre</td>
<td>The number of FTE staff employed by the Coordinating Centre.</td>
<td>identified that there could exist some double counting of staff. Data provided by the CRN regarding payroll costs is comprehensive.</td>
<td>We have used FTE data for CRN Coordinating Centre.</td>
<td>NIHR CRN</td>
<td>individuals only accounted for once)</td>
</tr>
<tr>
<td>MULTIPLIERS</td>
<td>Multipliers to estimate Indirect and Induced GVA</td>
<td>GVA and employment multipliers that enable an estimation of the indirect and induced impacts.</td>
<td></td>
<td>ONS &amp; Scottish Government</td>
<td></td>
</tr>
</tbody>
</table>

Source: KPMG analysis. 201
### Table 5: Metrics to estimate average per patient payment

<table>
<thead>
<tr>
<th>Metric</th>
<th>Description</th>
<th>Challenges with capturing</th>
<th>How we’ve captured</th>
<th>Source of information</th>
<th>Recommendations going forward</th>
</tr>
</thead>
</table>
| Planned per patient payment, total          | On a trial-by-trial basis, the total planned per patient payment as per the CRN commercial costing template. | Both the total and subtotal are extracted from the commercial costing templates. These are the associated challenges:  
   - Data on per patient payment is not usually held in an aggregate way by NHS Trusts. The information is instead held in individual costing templates and extracting relevant information is resource intensive.  
   - There are also some commercial sensitivities with NHS Trusts in providing commercial costing templates and in some cases, non-disclosure agreements were in place. | Extracted from the final costing templates as provided by seven NHS Trusts.     | NHS Trusts / CPMS (if final costing template is available)                        | P.1. Compulsory submission of finalized commercial costing templates                    |
| Planned subtotal per patient payment (ex. Indirect costs and capacity building) | On a trial-by-trial basis, the planned subtotal per patient. This relates only to the cost of staff time associated with the treatment of a patient. |                                                                                                                                                                                                                         | Extracted from the final costing templates as provided by seven NHS Trusts.     | NHS Trusts / CPMS (if final costing template is available)                        | P.2. NHS Trusts must submit per patient information to the CRN in an aggregate form.         |
| Actual per patient payment, total          | On a trial-by-trial basis, the total actual per patient payment. This should be derived from invoices sent to sponsor companies, and how many patients this relates to (i.e. recruitment). | Planned per patient payment information does differ from actual information. There is no consistent way this held by NHS Trusts.  
   This was not available on a trial-by-trial basis.  
   There were also commercial sensitivities with NHS Trusts providing this. | Provided by one NHS Trust only, where data was already held in an aggregate form. | NHS Trusts                                                                                       |                                                                                           |

Table 6: Metrics to capture the cost saving to the NHS

<table>
<thead>
<tr>
<th>Metric</th>
<th>Description</th>
<th>Challenges with capturing</th>
<th>How we’ve captured</th>
<th>Source of information</th>
<th>Recommendations going forward</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of pharmaceutical-based interventional trials where IMP replaces standard treatment</td>
<td>The proportion of pharmaceutical-based interventional studies where IMP replaces the standard treatment, and therefore representing a cost saving to the NHS (Scenario 3).</td>
<td>Information on whether the study treatment replaces the standard treatment is not clearly defined in protocols.</td>
<td>We have used study protocols to assess if the study being considered represents a cost saving to the NHS.</td>
<td>Protocols / Principal Investigators</td>
<td>D.1. Insert a compulsory field in the protocols, submitted to the CRN, which requires details on standard treatment to be detailed. D.2. Require NHS Trusts to estimate the cost of standard treatment on a per patient basis</td>
</tr>
<tr>
<td>Name and dosage of standard treatment drug</td>
<td>The name of the standard treatment drug, the maximum dosage and duration of treatment. This will be collected for each pharmaceutical-based interventional study where the IMP replaces the standard treatment.</td>
<td>There is no standard location within the study protocols where this information is recorded. In some cases, it is not possible to find the name of the standard treatment drug and these studies then had to be excluded from the sample.</td>
<td>We have used the study protocols, in the first instance, to extract information on the name, maximum dosage and duration of treatment of standard treatment drug. When this is not available in the study protocol, we cross-reference the study drug name with emc database to extract this information.</td>
<td>Protocols / Principal Investigators</td>
<td>emc database</td>
</tr>
<tr>
<td>Value of standard treatment drug</td>
<td>The value of the standard that would have been used in the absence of the study.</td>
<td>-</td>
<td>We use the Zenrx database to extract information on the value of the standard treatment drug. This is multiplied by dosage and duration of treatment to estimate the average cost saving per patient. We use the total number of patients recruited in the Portfolio estimated to receive a drug that provides a cost saving to the NHS.</td>
<td>Zenrx database</td>
<td></td>
</tr>
</tbody>
</table>

Source: KPMG analysis. 2016
Appendix 1  Technical annex

A1.1 Economic impact

Our analysis of the economic impact was conducted in line with methodologies set out in HM Treasury’s The Green Book: Appraisal and Evaluation in Central Government.\textsuperscript{122} It considered the economic impact of the clinical research activity supported by the National Institute of Health Research (NIHR) Clinical Research Network (CRN) in terms of direct, indirect and induced gross value added (GVA) and employment which is reported in terms of full-time equivalents (FTEs).

The clinical research activity supported by the CRN directly adds GVA to the UK economy through the employment it generates within NHS Trusts and other care providers, universities, sponsor companies, CROs and within the network itself. GVA at the industry or organisational level can be measured through two different approaches: the income approach and the production approach.\textsuperscript{123} Based on the data available to us, we have adopted the income approach in our analysis, which defines GVA as follows:

\[
\text{GVA} = \text{Net pre-tax profit} + \text{Compensation of Employees} + \text{Depreciation}
\]

We treated clinical research activity, both within the public sector and within individual private sector R&D teams, as non-profit making. We therefore approximated the GVA impact by using data on payroll costs, representing the employee compensation element of GVA. The payroll costs associated with those involved directly in clinical research therefore represent the direct GVA impact.

The direct employment is the number of FTEs employed directly by stakeholders involved in clinical research activity.

Through this direct activity, wider economic activity is generated in the associated supply chains. For example, this could include suppliers of medical supplies or providers of management information systems in the case of NHS Trusts and care providers. Each of these suppliers also has its own suppliers, and so the economic activity perpetuates across the economy. This activity generated through supply chains is the indirect GVA and employment generated by the CRN supported clinical research activity.

Induced GVA and employment are also generated through direct and indirect employees spending a proportion of their wages in the UK economy. As part of our economic framework, we also considered these induced impacts.

The economic analysis covers the economic impacts associated with:

- the operation of the CRN Coordinating Centre;
- non-commercial clinical research activity within NHS Trusts (provided for by the Local Clinical Research Network (LCRN) infrastructure);
- non-commercial clinical research activity within universities and charities;
- commercial clinical research activity within NHS Trusts; and
- commercial clinical research activity within pharmaceutical companies and contract research organisations (CROs).

Details of our approach to estimating the impacts for each of the stakeholder groups are detailed below.

**A1.1.1 Economic impact of the CRN Coordinating Centre**

Using data sourced directly from the CRN we used a bottom-up approach to estimate the economic impact of the CRN Coordinating Centre.

**GVA**

The CRN provided payroll cost data relating to the CRN Coordinating Centre for FY 2014/15 which we used as our estimate of direct GVA.

To estimate the indirect GVA, we used the Office for National Statistics (ONS) indirect GVA multipliers for the relevant Standard Industry Classification (SIC) code, 84, which relates to ‘Public Administration And Defence; Compulsory Social Security (Non-market)’\(^{124}\). We applied this using the following formula:

\[
Indirect GVA = Direct GVA \times \text{(sector specific Type I GVA multiplier)}^{125} \times \left(1 \right)
\]

We then estimated the induced GVA effects using the following formula:

\[
Induced GVA = \left[Direct GVA \times \text{(sector specific Type II GVA multiplier)}^{126}\right] - \left[Direct GVA \times \text{(sector specific Type I GVA multiplier)}^{127}\right]
\]

We used the sector specific Type I and Type II GVA multipliers sourced from the Scottish Government\(^{128}\) to estimate the induced effect as the ONS does not produce Type II multipliers.

**Employment**

To estimate the direct employment impact, in full time equivalent terms (FTE), we used data provided by the CRN relating to FTE employees of the Coordinating Centre. Due to the changes within the CRN in 2014, the data figure for 2014/15 did not include the Coordinating Centre staff. We used the figure for 2015/16 as a proxy.

In order to estimate the indirect employment we used the ONS indirect employment multipliers for the sector SIC code, as above, for the activity of the CRN and applied the following formula:

\[
Indirect employment = Direct employment \times \text{(sector specific Type I employment multiplier)}^{129} \times \left(1 \right)
\]

In addition to the indirect effect, we estimated the induced employment effects using the following formula:

---


\[
Induced\ employment
= \[\text{Direct employment} \times (\text{sector specific Type II employment multiplier}^{130} - 1)\]
- \[\text{Direct employment} \times (\text{sector specific Type I employment multiplier}^{131} - 1)\]
\]

A1.1.2 Economic impact of commercial activity

The economic impact of commercial research is generated through commercial clinical research activity within NHS Trusts and within commercial pharmaceutical companies and contract research organisations (CROs).

Using data sourced directly from NHS Trusts, we used a bottom-up approach to estimate the economic impact of commercial clinical research activity within NHS Trusts.

We were unable to obtain the required data directly from sponsor companies and CROs. We therefore adopted a top-down approach to estimate the economic impact of pharmaceutical companies and CROs, using publicly available industry level data.

A1.1.2.1 NHS Trusts

We estimated the economic impact as a result of commercial studies undertaken within NHS Trusts using the average ‘per patient payments’ received by the NHS Trusts. Details of our calculation of the average per patient payment can be found in Section 1.2.

GVA

We assume that NHS Trusts do not make any profit and therefore we used payroll costs as a proxy for the direct GVA generated. For 92 NHS Trusts we obtained a breakdown of costs for staff costs and non-staff costs was available. From this we estimated that staff costs make up, on average, 52 per cent of total clinical research costs. We multiplied this proportion by the total payment received by NHS Trusts for commercial clinical research to estimate the direct GVA figure.

We estimated the indirect and induced GVA in the same manner as for CRN activity using SIC code 86, ‘Human health services’^{132}.

Employment

To estimate the direct employment impact, in full time equivalent terms (FTE), we used the GVA estimate as above. We used the following formula, using SIC code 86, ‘Human health services’^{133}:

\[
\text{Direct employment} = \frac{\text{Direct GVA}}{\text{sector average GVA per employee}}
\]

---


We used the ONS data to estimate the GVA per employee based on the ‘Human health services’ sector, providing a figure of £50,499\textsuperscript{134}. We calculated the indirect and induced employment effects in the same manner as for CRN activity using SIC code 86.

A1.1.2.2 Pharmaceutical companies and CROs

We were unable to obtain data directly from pharmaceutical companies and CROs to undertake a bottom-up analysis. As an alternative, we used a top-down approach using the ONS UK Business Enterprise Research and Development dataset.\textsuperscript{135}

GVA

We used ONS data from the table titled ‘Current and capital expenditure on R&D performed in UK businesses: detailed product groups, 2014’. This provided the total payroll costs spend in the UK on R&D in the Pharmaceuticals sector.

As this is the total R&D spend, it is assumed that there is no profit on these activities, thus direct GVA is captured as payroll costs.

This R&D spend captures all types of R&D activity (including non-clinical research related spend) and for the whole of the UK (not only England). With this in mind, we transformed the data in the following ways:

- The proportion of R&D spent in England is assumed to be 91.7 per cent, taken from data in the table titled ‘Breakdown of R&D performed in UK businesses by country or region: expenditure and employment, 2003 to 2014 current prices’ which provided the breakdown of spend by each country.
- The proportion of R&D spent on clinical studies is assumed to be 49.8 per cent as per ABPI data.
- MedTech is an important element of clinical research activity however ONS data captures only the activity of pharmaceuticals. To ensure MedTech is not omitted from the estimation, we inflated the payroll costs by five per cent. This five per cent was based on data from MHRA regarding device approvals versus drug approvals.
- The proportion of R&D activity that is assumed to fall within the CRN Portfolio was 88 per cent. This is based on data collection undertaken as part of this report.

The total payroll costs, after these amendments, is the direct GVA associated with clinical research activity.

We calculated the indirect and induced effects using the same approach as previously described using SIC code 72, ‘Scientific research and development services’.\textsuperscript{136}

Employment

The ONS table titled ‘Employment in R&D performed in UK businesses: detailed product groups, 2014’ provided the total FTE figure for the UK in R&D in the Pharmaceuticals sector. We adjusted this

\textsuperscript{134} To estimate the sector average GVA per employee, in GVA terms, we had to first estimate the number of FTEs for each SIC code as the ONS does not publish FTE breakdown by industry. We estimated this using total employment figures from the ONS Business Register and Employment Survey 2014, which states both full-time and part-time employment figures which was converted to FTE using the same approach as above. This figure was then used to estimate the GVA per FTE.

\textsuperscript{135} Business Enterprise Research and Development Statistical Bulletins. 2014. Available at: http://www.ons.gov.uk/economy/governmentpublicsectorandtaxes/researchanddevelopmentexpenditure/bulletins/businessenterpriseresearchanddevelopment/previousReleases

figure in the same way as for payroll costs, to capture only the effect of clinical studies in England in the CRN Portfolio and to include MedTech. This provided us with a direct employment estimate.

We calculated the indirect and induced employment effects using the same approach as the CRN activity using SIC code 72, ‘Scientific research and development services’.\(^{137}\)

**A1.1.3 Economic impact of non-commercial activity**

**A1.1.3.1 NHS Trusts**

Using data directly sourced from the LCRN, we were able to construct a bottom-up approach to estimate the economic impact of non-commercial clinical research activity supported by LCRN resource.

**GVA**

We calculated the direct, indirect and induced GVA in the same manner as for CRN activity, based on LCRN payroll data and using indirect and induced GVA multipliers associated with SIC code 86, ‘Human health services’.\(^{138}\)

**Employment**

We calculated the indirect and induced employment effects using the same approach as the CRN activity, based on LCRN employment data and using indirect and induced employment multipliers associated with SIC code 86, ‘Human health services’.\(^{139}\)

**A1.1.3.2 Universities and lead investigators**

We estimated the economic impact of the non-commercial clinical research activity undertaken within universities and by lead investigators using total grant payments. Based on stakeholder consultation undertaken as part of this report, we assumed that all of the grant received was spent on payroll costs.\(^{140}\) We sourced data on total grant payments from the UK Clinical Research Collaboration (UKCRC).\(^{141}\)

**GVA**

Using data from the UK CRC, which comprises all grants provided for health research in the UK, we were able to estimate the value of grants for clinical studies in for FY 2014/15. This database contains all grants awarded in the UK for all purposes, however allows the data to be filtered by research activity.

In order to obtain grant data relating only to clinical study activity we used the following research activity codes to filter the data: \(^{142}\)

- 4.2, ‘Detection, Screening and Diagnosis’; Evaluation of markers and technologies

---


\(^{140}\) Researchers and CRN personnel indicated the grant award covered the research costs of a study which was predominantly spent on funding staff.

\(^{141}\) UKCRC Health Research Classification System. 2014. Available at: [http://www.hrcsonline.net/pages/data](http://www.hrcsonline.net/pages/data)

\(^{142}\) UKCRC Health Research Classification System. 2014. Available at: [http://www.hrcsonline.net/rac/overview](http://www.hrcsonline.net/rac/overview)
- 5.1-5.8, ‘Development of Treatment and Therapeutic Interventions’, all except for Resources and infrastructure
- 6.1-6.8, ‘Evaluation of Treatments and Therapeutic Interventions’, all except for Resources and infrastructure

We summed the annualised grant values across all grants which met the following criteria:

- awarded in FY 2014/15;
- awarded for the relevant research activity codes (as above); and
- awarded to NHS Trusts in England only.

This yielded the total grants awarded for 2014/15 relating to clinical research in England.

Using data compiled from five NHS Trusts and LCRNs143 we found that, on average, 62 per cent of all non-commercial clinical studies are part of the CRN Portfolio. We applied this to the total value of grants awarded, as a proxy for total payroll costs, to estimate the direct GVA.

We calculated the indirect and induced GVA in the same manner as for CRN activity using indirect and induced GVA multipliers associated SIC code 86, ‘Human health services’.144

**Employment**

We calculated the direct, indirect and induced employment effects using the same approach as for the commercial study impact, using average GVA per employee for SIC code 86 for direct and relevant employment multipliers to calculate the indirect and induced employment.

**A1.2 Estimating per patient payment**

Previous work carried out by the CRN to generate estimates of the average per patient payment to NHS Trusts found information to be incomplete and not easily accessible. An internal piece of work undertaken in January 2016 looked to identify the average per patient payment relating to commercial studies. Commercial study costing templates145 were used as the source of collecting this information. This work identified that many study records held by the CRN146 did not include final costing templates. In cases where costing templates were available, the study team said they were difficult to find within the database due to the quantity of files held for each study and inconsistency in the labelling of files.

Noting these challenges, we approached NHS Trusts directly to gather further information. Although we recognise other bodies also deliver studies (for example, primary care providers such as GP surgeries), the focus for this piece of work focused on gathering information from NHS Trusts. Table 7 details the information we requested from NHS Trusts and how it was used.

**Table 7: Request to NHS Trusts for per patient payment information**

<table>
<thead>
<tr>
<th>What we requested</th>
<th>Why we requested</th>
</tr>
</thead>
</table>

143 We requested data on the number of Portfolio and non-Portfolio studies from LCRNs and NHS Trusts.
144 Detailed descriptions of the SIC codes and relevant multipliers used can be found in Section 1.4
145 The commercial study costing templates provide a framework for transparent cost display and calculation to support swift local site budget negotiations when performing commercial studies in the NHS. This is provided by the CRN.
146 The CRN hold records on studies in the NIHR Coordinated System for gaining NHS permissions (CSP) database as well as the Central Portfolio Management System (CPMS) database.
<table>
<thead>
<tr>
<th>Total budget estimated per patient</th>
<th>This is the total per patient payment expected for the study and represents what will be received by the NHS Trust for each patient recruited. We can scale up using the average per patient payment to the number of patients recruited across the commercial CRN Portfolio.</th>
</tr>
</thead>
<tbody>
<tr>
<td>On a per patient basis, the subtotal for both indirect costs and capacity building included in the total budget</td>
<td>This subtotal captures the indirect costs (which cover overheads) and the capacity building element which is ring fenced to build research resources within the NHS Trust (20 per cent of direct staff costs). This is important to understand how much money is put aside for capacity building within NHS Trusts. We can also estimate direct staff costs per patient by: Total budget – indirect costs – capacity building. This direct staff cost is used for the economic impact assessment, as described in Section 5.1.</td>
</tr>
<tr>
<td>Total staffing hours per patient for research procedures</td>
<td>This direct staffing time is used to estimate the employment impact for commercial studies for NHS Trusts and other care providers – as described in Section 5.1.</td>
</tr>
</tbody>
</table>


We approached ten NHS Trusts as part of this study and received a sample of costing templates or aggregate data capturing the above variables from seven NHS Trusts. These NHS Trusts vary in size in terms of their research capacity and have a geographical spread across England, including representation both within and outside of London.

Data was provided by seven different NHS Trusts on planned and actual per patient data for clinical studies that had taken place at their site. This enabled us to gather information on 3402 different studies, of which 325 provided information on the planned per patient payment and 81 included the actual per patient payment received. We sourced this data from the costing templates agreed between the NHS Trust and the commercial sponsor or CRO.

These payments were negotiated in previous years and therefore needed to be adjusted to the present value.147

— We discount the values to 2016 prices using the social discount rate of 3.5 per cent, as per HM Treasury’s Green Book guidance.148 This was done based on the start date of the study. For example, if a study started in 2011 the per patient payment was discounted to account for the five years that have elapsed between 2011 and 2016.149

— The value then had to be adjusted to inflation, to represent the real value, and as such the appropriate inflation factor was used150. This similarly was done based on the start date of the study.

An average of the 325 per patient payments, in present value terms, were calculated to give an average of £6,558. We also estimated the median value and mapped this to understand if there was any skewness in the data.

Using data provided by the CRN on actual recruitment figures for the relevant studies, we calculated the average recruitment per year per study. This reflects that recruitment is undertaken for the duration of the study. To estimate the annual revenue, we estimated recruitment on a per year basis. We recognise that recruitment will often be front loaded, however detailed data on recruitment by year was not available therefore an average annual figure was used. We summed the average recruitment

147 The social discount rate of 3.5%, as per HMT’s Green Book, was used to convert the per patient payment into present value terms.
149 Where no start date was available the study was assumed to have started within the last year and thus discounted by one year.
150 The IMF historical inflation rates were to adjust for actual inflation.
per year across all studies that took place in FY 2014/15 to obtain the total number of patients which we estimated to be 29,195.

We then calculated the total payment received by NHS Trusts for commercial studies using the following formula:

\[
\text{Total payments received} = \text{Average per patient payment} \times \text{total number of patients}
\]

Based on the information extracted against the above variables, we estimated the average per patient payment across all studies. We considered how this varies by different types of studies, particularly by:

- the clinical specialty\(^{151}\) the study falls within;
- whether a study is interventional\(^{152}\) or observational\(^{153}\) in nature; and
- the phase\(^{154}\) of the study.

We also identified the proportion of the total per patient payment that are made up of indirect costs and capacity building.

### A1.3 Estimating the pharmaceutical cost saving to the NHS

In many studies, particularly in the case of randomised controlled trials (RCTs), there is ‘clinical equipoise’, meaning that there is substantial uncertainty about the expected efficacy of the drug being trialled. For most studies, this means the main source of impact will be the cost saving to the NHS where the study treatment replaces the standard treatment.

These cost savings are relevant for industry-sponsored interventional studies using drug-products. Since 2010 a total of 2,059 interventional commercial drug studies and 582 interventional industry-sponsored drug studies have been entered onto the CRN Portfolio\(^{155}\).

Not all industry-sponsored studies result in a cost saving – in some cases, the study drug may be used in conjunction with the standard treatment drug so the standard treatment cost is still incurred by the NHS. In other cases, there may be no drug used as part of the standard treatment so in this instance the use of the study drug does not represent any drug cost saving. A cost saving only occurs when the use of study treatment drug replaces the use of a standard treatment drug.

These three scenarios are mapped out in Figure 17: Scenarios of cost saving to the NHS below. The scenario where cost savings to the NHS will be attributed is highlighted in red.

---

\(^{151}\) There are 30 different main clinical specialties that a study can fall into. A full list of these specialties can be found here: [http://nuhrise.org/wp-content/uploads/NIHR-CRN-specialties-themes-and-operational-divisions-map.pdf](http://nuhrise.org/wp-content/uploads/NIHR-CRN-specialties-themes-and-operational-divisions-map.pdf)

\(^{152}\) An interventional study is when participants are assigned to receive one or more interventions (or no intervention) so clinicians can evaluate the effects of that intervention.

\(^{153}\) An observational study is when individuals are observed, or certain outcomes are measured. No attempt is made to affect the outcome.

\(^{154}\) Clinical research is divided into different stages, called phases. The earliest phases generally look at an intervention’s safety and the side effects it causes. Later phase studies generally test whether a new treatment is better than an existing treatment.

\(^{155}\) The CRN provided KPMG the study summary database on 08 March 2016. These figures correspond to this date.
In our approach to estimating the cost saving, we first considered which Scenario the study relates to. For those relative to Scenario 3, we used the study protocol to extract information on the name of the standard treatment drug, the maximum dosage and the duration of treatment. We then used Zenrx, a pricing database for approved pharmaceutical products, to extract information on the price for the standard treatment. This approach is detailed below in Figure 18.

**Table 8: Sources of information to estimate drug value**

<table>
<thead>
<tr>
<th>Databases used for data extraction</th>
<th>Pricing database for approved pharmaceutical products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zenrx database</td>
<td>This database contains pricing information for approved products in a number of countries, including the UK. It is searchable based on compound and active ingredient, brand name or by manufacturer / distributor. It returns information on the quantity, unit and price (in GBP).</td>
</tr>
</tbody>
</table>
Databases used for data extraction

<table>
<thead>
<tr>
<th>Database</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>emc database</td>
<td><strong>Prescribing information for licensed medicines</strong></td>
</tr>
<tr>
<td></td>
<td>This database contains up-to-date information on prescribing information for</td>
</tr>
<tr>
<td></td>
<td>licensed medicines. It draws on summaries of product characteristics and</td>
</tr>
<tr>
<td></td>
<td>patient information leaflets.</td>
</tr>
<tr>
<td></td>
<td>This database is used if the study protocol did not contain information on</td>
</tr>
<tr>
<td></td>
<td>maximum dosage and/or duration of treatment for the named standard</td>
</tr>
<tr>
<td></td>
<td>treatment drug.</td>
</tr>
</tbody>
</table>


We extracted and collated information on a sample of 155 studies across all specialties. We also carried out a deep dive into the oncology specialty based on a sample of 150 cancer-specific studies.

We used the data extracted for the two samples to estimate the average cost saving for each. We then undertook analysis of how this varied by specialty and phase.

We used the average cost saving to scale up to estimate the saving for all drug-based industry-sponsored interventional studies in the CRN Portfolio expected to have a cost saving. 

156 From the sample of 155 studies considered for all specialties and 150 for oncology, we will know the proportion of studies that will represent a cost saving (i.e. Scenario 3). This proportion will be applied to the number of all drug-based industry-sponsored interventional studies to estimate the volume of studies for which there is a cost saving to the NHS.
Appendix 2  Stakeholder interview questions

This appendix details the stakeholder interview questions for:

— NHS Trusts
— Pharmaceutical and Medical Device companies
— CROs
— Charities
— CRN personnel

NHS Trusts

Introduction

We are undertaking a study to understand the value of the clinical research market for the UK and how the CRN contributes to this.

As part of this, we are working towards quantifying three key impacts:

- An estimate of the average per patient payment for commercial studies.
- An estimate of the cost saving for the NHS due to the drugs and devices used in clinical research.
- An estimate of the economic impact of clinical research activity in the UK.

We are also looking to undertake a qualitative assessment of:

- The contribution of the CRN to the impact of pharmaceuticals and technology in the NHS.
- The value added of the CRN activity.

To better understand the economic impact of clinical research activity and how the CRN adds value, we are speaking with a range of stakeholders. We will use this qualitative information to inform our findings and to feed into our final report.

Please note, we will obtain sign off from yourself, or an alternative appropriate contact, before presenting any views expressed in this interview.

Your role

1. How would you describe your role at your NHS Trust?

2. Are you involved with any day-to-day engagement with the CRN?

Your views on the value of clinical research activity
3. In your view, what are the main economic, social and/or health benefits of clinical research activity:

Prompt if needed to consider in terms of:

a. benefits to patients, NHS Trusts, society, economy;

b. economic activity (jobs / sector growth), inward investment, NHS Trust income and cost savings;

c. health and economic impacts of pharmaceutical / technology in the NHS for example through evidence-based prescribing, changed treatment pathways;

d. any other sources of impact.

3. Do you have specific examples of where you have seen these impacts?

Your views on the way CRN has influenced your organisation and the clinical research market

4. What proportion of all clinical research your NHS Trust undertakes are part of the CRN Portfolio?

5. In your view, what are the main ways in which the CRN adds value in terms of clinical research? What has your NHS Trust benefited most from? Can you give specific examples?

6. Does the value, and ways in which the CRN adds value, differ across studies? For example, between non-commercial and commercial studies?

7. What are your views on what the clinical research landscape would look like in the absence of the CRN:

   a. in terms of the volume of studies you are involved with?

   b. in terms of how studies would deliver in terms of number of participants?

   c. how long would it take to recruit and complete a study?

   d. the economic, social and/or health benefits of clinical research?

8. Has the development of the CRN changed any decision-making at your NHS Trust regarding investment in clinical research? Or the volume of clinical research activity being undertaken?

9. In your opinion, has it impacted on the way in which pharmacos undertake clinical studies and their decision-making regarding clinical research?

Costs of studies
10. How do the costs of clinical studies vary? What are the most important cost-differentiating factors?  
*Prompt: we currently think this is commercial/non-commercial, participant numbers, intervention type and phase of study.*

11. Does each stakeholder involved in clinical research absorb the right amount of costs?  
I.e. are the costs incurred proportionate to the benefits for the stakeholders?

**Wider observations**

12. Are you aware of any similar CRN models operating internationally? How are they similar / different?

13. Do you have any observations or ideas on potential future direction for the CRN to add greater value to the clinical research sector and the UK more widely?

**Pharmaceutical and Medical Device companies**

**Introduction**

We are undertaking a study to understand the value of the clinical research market for the UK and how the CRN contributes to this.

As part of this, we are working towards quantifying three key impacts:

- An estimate of the average per patient payment for commercial studies.
- An estimate of the cost saving for the NHS due to the drugs and devices used in clinical research.
- An estimate of the economic impact of clinical research activity in the UK.

We are also looking to undertake a qualitative assessment of:

- The contribution of the CRN to the impact of pharmaceuticals and technology in the NHS.
- The value added of the CRN activity.

To better understand the economic impact of clinical research activity and how the CRN adds value, we are speaking with a range of stakeholders. We will use this qualitative information to inform our findings and to feed into our final report.

Please note, we will obtain sign off from yourself, or an alternative appropriate contact, before presenting any views expressed in this interview.

**Your role**

1. How would you describe your role at within your company?

2. Are you involved with any day-to-day engagement with the CRN?
Your views on the value of clinical research activity

3. In your view, what are the main economic, social and/or health benefits of clinical research activity:

Prompt if needed to consider in terms of:

a. benefits to patients, NHS Trusts, society, economy;

b. economic activity (jobs / sector growth), inward investment, NHS Trust income and cost savings;

c. health and economic impacts of pharmaceutical / technology in the NHS for example through evidence-based prescribing, changed treatment pathways;

d. any other sources of impact.

Your views on the way CRN has influenced your company and the clinical research market

4. What proportion of all clinical studies your company undertakes are part of the CRN Portfolio?

5. In your view, what are the main ways in which the CRN adds value in terms of clinical research? What has your company benefited most from? Do you have any specific examples?

6. What are your views on what the clinical research landscape would look like in the absence of the CRN:

   a. in terms of the volume of research you are involved with?
   
   b. in terms of how studies would deliver in terms of number of participants?
   
   c. how long would it take to recruit and complete a study?
   
   d. the economic, social and/or health benefits of clinical research?

7. Has the development of the CRN changed any decision-making at your company regarding the attractiveness of the UK as a location for clinical research? Or, regarding the volume of activity being undertaken? Do you have any specific examples?

8. Have you made any other strategic decisions linked to the activity of the CRN?

Costs of studies

9. How do the costs of clinical studies vary? What are the most important cost-differentiating factors?

   Prompt: we currently think this is participant numbers, intervention type and phase of study.
10. Does each stakeholder involved in clinical research absorb the right amount of costs? I.e. are the costs incurred proportionate to the benefits for the stakeholders?

Wider observations

11. Are you aware of any similar CRN models operating internationally? How are they similar / different?

12. Do you have any observations or ideas on potential future direction for the CRN to add greater value to the clinical research sector and the UK more widely?

Contract Research Organisations (CROs)

Introduction

We are undertaking a study to understand the value of the clinical research market for the UK and how the CRN contributes to this.

As part of this, we are working towards quantifying three key impacts:

- An estimate of the average per patient payment for commercial studies.
- An estimate of the cost saving for the NHS due to the drugs and devices used in clinical research.
- An estimate of the economic impact of clinical research activity in the UK.

We are also looking to undertake a qualitative assessment of:

- The contribution of the CRN to the impact of pharmaceuticals and technology in the NHS.
- The value added of the CRN activity.

To better understand the economic impact of clinical research activity and how the CRN adds value, we are speaking with a range of stakeholders. We will use this qualitative information to inform our findings and to feed into our final report.

Please note, we will obtain sign off from yourself, or an alternative appropriate contact, before presenting any views expressed in this interview.

Your role

1. How would you describe your role within your company?

2. Are you involved with any day-to-day engagement with the CRN?

Your views on the value of clinical research activity

3. In your view, what are the main economic, social and/or health benefits of clinical research activity:
Prompt if needed to consider in terms of:

a. benefits to patients, NHS Trusts, society, economy;

b. economic activity (jobs / sector growth), inward investment, NHS Trust income and cost savings;

c. health and economic impacts of pharmaceutical / technology in the NHS for example through evidence-based prescribing, changed treatment pathways;

d. any other sources of impact.

Do you have specific examples of where you have seen these impacts?

Your views on the way CRN has influenced your company and the clinical research market

1. What proportion of all clinical research your company undertakes are part of the CRN Portfolio?

2. In your view, what are the main ways in which the CRN adds value in terms of clinical research? What has your CRO benefited most from? Can you provide any specific examples?

3. What are your views on what the clinical research landscape would look like in the absence of the CRN:

   a. in terms of the volume of studies you are involved with?
   
   b. in terms of how studies would deliver in terms of number of participants?
   
   c. how long would it take to recruit and complete a study?
   
   d. the economic, social and/or health benefits of clinical research?

4. Has the activity of the CRN changed any decision-making within your CRO regarding the attractiveness of the UK as a location for clinical research? Or, regarding the volume of activity being undertaken?

5. Has your CRO made any other strategic decisions linked to the activity of the CRN?

Costs of studies

6. How do the costs of clinical studies vary? What are the most important cost-differentiating factors?
   
   Prompt: we currently think this is participant numbers, intervention type and phase of study.

7. Does each stakeholder involved in clinical research absorb the right amount of costs? I.e. are the costs incurred proportionate to the benefits for the stakeholders?
Wider observations

8. Are you aware of any similar CRN models operating internationally? How are they similar / different?

9. Do you have any observations or ideas on potential future direction for the CRN to add greater value to the clinical research sector and the UK more widely?

Charities

Introduction

We are undertaking a study to understand the value of the clinical research market for the UK and how the CRN contributes to this.

As part of this, we are working towards quantifying three key impacts:

- An estimate of the average per patient payment for commercial studies.
- An estimate of the cost saving for the NHS due to the drugs and devices used in clinical research.
- An estimate of the economic impact of clinical research activity in the UK.

We are also looking to undertake a qualitative assessment of:

- The contribution of the CRN to the impact of pharmaceuticals and technology in the NHS.
- The value added by the CRN activity.

To better understand the economic impact of clinical research activity and how the CRN adds value, we are speaking with a range of stakeholders. We will use this qualitative information to inform our findings and to feed into our final report.

Please note, we will obtain sign off from yourself, or an alternative appropriate contact, before presenting any views expressed in this interview.

Your role

1. How would you describe your role within your organisation?

2. Are you involved with any day-to-day engagement with the CRN?

Your views on the value of clinical research activity

3. In your view, what are the main economic, social and/or health benefits of clinical research activity:

Prompt if needed to consider in terms of:
a. benefits to patients, NHS Trusts, society, economy;

b. economic activity (jobs / sector growth), inward investment, NHS Trust income and cost savings;

c. health and economic impacts of pharmaceutical / technology in the NHS for example through evidence-based prescribing, changed treatment pathways;

d. any other sources of impact.

4. Do you have specific examples of where you have seen these impacts?

Your views on the way CRN has influenced your organisation and the clinical research market

5. What proportion of all clinical studies your organisation undertakes are part of the CRN Portfolio?

6. In your view, what are the main ways in which the CRN adds value in terms of clinical research? What has your organisation benefited most from? Do you have any specific examples?

7. What are your views on what the clinical research landscape would look like in the absence of the CRN:
   a. in terms of the volume of studies you are involved with?
   b. in terms of how studies would deliver in terms of number of participants?
   c. how long would it take to recruit and complete a study?
   d. the economic, social and/or health benefits of clinical research?

8. Has the activity of the CRN changed any decision-making within your organisation regarding the attractiveness of the UK as a location for clinical research? Or, regarding the volume of activity being undertaken?

9. Has your organisation made any other strategic decisions linked to the activity of the CRN?

Costs of studies

10. How do the costs of clinical studies vary? What are the most important cost-differentiating factors?
    Prompt: we currently think this is participant numbers, intervention type and phase of study.
11. We understand charities need to cover Part A of AcoRD costs through grant funding (with activities listed in Part B undertaken by existing staff employed by NHS, CRN or other organisation if applicable). In your view, is this set up to split costs efficient and/or appropriate?

Prompt: do you think these costs are proportionate to the benefits?

Wider observations

12. Are you aware of any similar CRN models operating internationally? How are they similar / different?

13. Do you have any observations or ideas on potential future direction for the CRN to add greater value to the clinical research sector and the UK more widely?

CRN personnel

Introduction

We are undertaking a study to understand the value of the clinical research market for the UK and how the CRN contributes to this.

As part of this, we are working towards quantifying three key impacts:

- An estimate of the average per patient payment for commercial studies.
- An estimate of the cost saving for the NHS due to the drugs and devices used in clinical research.
- An estimate of the economic impact of clinical research activity in the UK.

We are also looking to undertake a qualitative assessment of:

- The contribution of the CRN to the impact of pharmaceuticals and technology in the NHS.
- The value added of the CRN activity.

To better understand the economic impact of clinical research activity and how the CRN adds value, we are speaking with a range of stakeholders. We will use this qualitative information to inform our findings and to feed into our final report.

Please note, we will obtain sign off from yourself, or an alternative appropriate contact, before presenting any views expressed in this interview.

Your role

157 This includes costs such as screening, coordination and management, investigations, follow-up, cash reimbursements, costs of placebos, data storage, training, data analysis etc.
158 This includes, for example, local study trial co-ordination and management, data collection needed to answer the questions the research study is addressing and regulatory preparation and compliance.
1. How would you describe your role at the CRN?

2. Are you involved with any day-to-day engagement with clinical research providers?

Your views on the value of clinical research activity

3. In your view, what are the main economic, social and/or health benefits of clinical research activity?

Prompt if needed to consider in terms of:

   a. benefits to patients, NHS Trusts, society, economy;

   b. economic activity (jobs / sector growth), inward investment, NHS Trust income and cost savings;

   c. health and economic impacts of pharmaceutical / technology in the NHS for example through evidence-based prescribing, changed treatment pathways;

   d. any other sources of impact.

Your views on the way CRN influence the clinical research market

4. In your view, what are the main ways in which the CRN adds value in terms of clinical research?

5. What do you consider have been the main changes in terms of benefits and impacts seen since its inception in 2006?

6. Does the value, and ways in which the CRN adds value differ for non-commercial and commercial studies?

7. What are your views on what the clinical research landscape would look like in the absence of the CRN:

   a. In terms of the volume of studies?

   b. In terms of how studies would deliver in terms of number of participants?

   c. How long it would take to recruit and complete a study?

   d. The economic, social and/or health benefits of clinical studies?

8. Do you think the development of the CRN has had an impact on pharmacos and their decision-making regarding conducting clinical research or investing in the UK? What is your basis for this view?

9. Do you think the development of the CRN has had an impact on non-commercial stakeholders and their decision-making? What is your basis for this view?

Costs of studies
This section may only be relevant to some NIHR personnel – should be filtered based on responses to Section 1.1.

10. How do the costs of clinical studies vary? What are the most important cost-differentiating factors?
   Prompt: we currently think this is commercial / non-commercial, participant numbers, intervention type and phase of study.

11. In your view, is the way costs are currently allocated in terms of responsibility for funding (i.e. study support costs, NHS treatment costs and research costs) appropriate?

12. Does each stakeholder absorb the right amount of costs? I.e. are the costs incurred proportionate to the benefits for stakeholders?

Wider observations

13. Are you aware of any similar CRN models operating internationally? How are they similar / different?
Contact us

Simon Trussler
Director, Economics & Regulation
T: +44 (0)20 7694 5497
E: simon.trussler@kpmg.co.uk

Ruth Beckett
Manager, Economics & Regulation
T: +44 (0)20 7311 3063
E: ruth.beckett@kpmg.co.uk

www.kpmg.com

© 2016 KPMG LLP, a UK limited liability partnership, is a subsidiary of KPMG Europe LLP and a member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative, a Swiss entity. All rights reserved.

The information contained herein is of a general nature and is not intended to address the circumstances of any particular individual or entity. Although we endeavour to provide accurate and timely information, there can be no guarantee that such information is accurate as of the date it is received or that it will continue to be accurate in the future. No one should act on such information without appropriate professional advice after a thorough examination of the particular situation.

The KPMG name and logo are registered trademarks or trademarks of KPMG International Cooperative.