Impact and value of research supported by NHS organisations in Wales

A KPMG report to Health and Care Research Wales

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Foreword

Health and Care Research Wales is pleased to support the publication of this report which showcases the impact and value of research supported by NHS organisations in Wales.

In 2019, Health and Care Research Wales commissioned KPMG to undertake an independent analysis to assess the economic impact and value generated through the delivery of health research activity undertaken in Wales over the financial year 2018/19, including the gross value added (GVA) and jobs created as a result of commercial and non-commercial research undertaken by NHS organisations.

As can be seen from the report, in 2018/19, an estimated total of £93 million in GVA and approximately 1,600 full time equivalent jobs were supported by NHS Wales supported health research activity, which clearly demonstrates the impact health research has on the wealth and prosperity of the nation.

Analysis reflects the economic contribution a point in time, but interpreting its contents in our current context is important – as much has changed since 2018/19. I came into post as the new Director for Health and Care Research Wales in October 2019 and we have re-commissioned our Health and Care Research Wales infrastructure. And of course, the COVID19 pandemic has changed the landscape and demonstrated the value and impact of health and social care research in a way that we could never have imagined. The NHS organisations in Wales did an outstanding job in responding to that challenge, supporting urgent public health studies in an efficient and timely way and we implemented changes rapidly in the Support & Delivery Service (locally and nationally) – to process, systems and structures to support that.

It is within this context that this report on the “Impact and value of research supported by NHS organisations in Wales” is published. It is intended to be a baseline report for policy use and for NHS organisations to use to understand the economic impact and value of the health research they support.

This report is one of a number of ways which we demonstrate impact and value of health and social care research, clearly demonstrating the positive impact research has on the health and wellbeing of the Welsh population, and also includes through our Health and Care Research Wales Impact Report, Annual Report 2019/20, the launch of our new website and our digital Health and Care Research Wales Conference in October 2020, with a focus on making a difference; the impact of health and social care research.

As we move into a new strategic period with an updated Health and Care Research Wales strategy for the next five years, reports such as this demonstrating the economic impact and value of health research, will help to inform the future as we move forward into our new world.

Kieran Walshe

Director of Health and Care Research Wales
Contents

Executive Summary 4

About the study and the framework for analysis 4

Key findings: the economic contribution of health research activity supported by NHS organisations 5

Key findings: the monetary value to the NHS associated with the Health and Care Research Wales Portfolio of health research studies 5

Key findings: the added value of the Support & Delivery Service 6

1 About this study 9

1.1 Scope of this study 9

1.2 Context: Health and social care research in Wales 10

2 The framework for assessing the impact and value of health research 15

2.1 Approach to estimating the economic contribution of the health research activity 15

2.2 Approach to estimating the monetary value to the NHS of health research activity 16

2.3 Approach to assessing added value 18

2.4 Data sources and limitations 19

3 The economic contribution of health research activity supported by NHS organisations in Wales 21

3.1 GVA and employment impacts 21

3.2 Monetary value to NHS organisations of health research activity 26

4 The added value of the Support & Delivery Service 31

4.1 The Welsh research environment 31

4.2 Stakeholders’ views on the value added by the Support & Delivery Service 32
Executive Summary

About the study and the framework for analysis

Health and Care Research Wales is a national virtual organisation in Wales, funded by the Welsh Government’s Research & Development Division. It consists of several distinct elements of research development and delivery infrastructure. It runs competitive funding schemes, including cross funder initiatives, investment in UK wide programmes and manages resources to promote, support and deliver health and social care research. Its vision is for Wales to be “internationally recognised for excellent health and social care research that has a positive impact on the health, wellbeing and prosperity of the people in Wales”.1

Health and Care Research Wales’ activities include the Support and Delivery Service (the “S&D Service”), which is a Wales-wide service providing a range of support functions to researchers, NHS organisations and the public with the aim of ensuring that infrastructure is in place to deliver health and social care research studies across Wales.2 It also manages a comprehensive portfolio (the “Portfolio”) of health and social care research undertaken in Wales funded by a range of public, charitable and commercial research funders.

In 2019, Health and Care Research Wales commissioned KPMG to undertake a study analysing the economic impact and value generated through the health research activity undertaken in Wales over the financial year (“FY”) 2018/19. The study focuses on the following areas of impact:

1 the overall economic contribution associated with the delivery of health research studies on the Portfolio, measured in terms of gross value added3 (“GVA”) and full time equivalent (“FTE”) employment;

2 the monetary value to NHS Wales resulting from delivery of health research, specifically the direct cost savings associated with drugs being provided free of charge by sponsor companies during clinical studies and the commercial income payments to NHS organisations4 for the delivery of clinical studies; and

3 the wider impacts in the health and social care research market generated by the S&D Service’s activities and contributions made by the S&D Service, such as through its provision of study support and its database of study-level data.

Our study provides a quantitative and qualitative assessment of these impacts in gross terms5, drawing on primary data collected for the study, publicly available data and information, and insights gathered through a series of stakeholder interviews. Full details of our scope of work, approach, data sources, and limitations to the study are included in Section 2 of the report.

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1 Health and Care Research Wales Aims and Objectives. See: https://www.healthandcareresearch.gov.wales/aims-and-objectives/aims-and-objectives/


3 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 activity.

4 In Wales there are seven Local Health Boards, and three NHS Trusts. For simplicity, in this study we define the seven Local Health Boards and the three NHS Trusts as NHS organisations.

5 Gross impacts reflect the total effect of an intervention or activity. Net impacts take into account only those impacts that are additional, i.e. impacts that are brought about, over and above what would happen anyway. See: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/191511/Additionality_Guide_0.pdf
Key findings: the economic contribution of health research activity supported by NHS organisations

Our analysis, detailed in Section 3 of this report, indicates that in FY 2018/19, an estimated total of £93 million in GVA and approximately 1,600 FTE jobs were supported by NHS organisations-supported health research activity. This includes the direct GVA and employment impacts from the health research activity and activities within the S&D Centre, as well as those generated in the United Kingdom (“UK”) supply chain (indirect effects) and in the wider economy, through spending by employees (induced effects). The split of this across types of commercial and non-commercial research and the contribution of the S&D Centre itself is shown in Figure 1 below.

Figure 1: Economic impact of NHS organisations-supported health research in FY 2018/19

Key findings: the monetary value to the NHS associated with the Health and Care Research Wales Portfolio of health research studies

Payments to NHS organisations by industry sponsors

When conducting commercial health studies, secondary care providers (such as NHS organisations) and primary care providers (such as GP practices) receive income for delivering commercial health research to compensate for the costs associated with delivering the research, as well as to enable investment in research capacity and capability longer term.\(^6\)

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\(^6\) 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.

\(^7\) Non-commercial studies are initiated by non-commercial researchers. These studies are usually paid for with grant funding from charities, Government or other not-for-profit organisations. However, the category of non-commercial clinical research also includes ‘investigator-initiated trials’ (iITs). These are sponsored by an NHS Organisation or university (which, therefore, retain the intellectual property rights for the study) but which receive funding or free drugs from a commercial company.

\(^8\) This is known as capacity building and represents an allowance of 20% on top of costs. See: NIHR (2017). User manual for the NIHR CRN Industry Costing Template. See: [https://www.nihr.ac.uk/funding-and-support/documents/study-support-service/Early-contact-and-engagement/Costing-Templates/USER%20MANUAL%20%20Industry%20Costing%20Template%20MAY%202017.pdf](https://www.nihr.ac.uk/funding-and-support/documents/study-support-service/Early-contact-and-engagement/Costing-Templates/USER%20MANUAL%20%20Industry%20Costing%20Template%20MAY%202017.pdf)
Based on data obtained from the seven NHS organisations in Wales which undertook commercial studies on the Portfolio in FY 2018/19, covering 119 site level payments\(^9\), we estimate the average payment, on a per patient basis, was £11,873 in FY 2018/19.

By aggregating the per patient payments for these seven NHS organisations, we estimate that the total value of payments relating to the delivery of commercial clinical research supported by the NHS organisations reached approximately £7.4 million in FY 2018/19.

**Cost savings to the NHS**

In addition to the commercial revenues NHS organisations receive for conducting commercial health research studies, there are some direct cost savings to NHS organisations that arise where the sponsor companies provide drugs free of charge for clinical studies and these replace the standard treatments that would otherwise have been administered and paid for by the NHS organisations. Our analysis estimated that this scenario occurred in around 24% of commercial studies on the Portfolio, and 6% of non-commercial studies on the Portfolio.\(^10\)

Our analysis estimates an average pharmaceutical cost saving to the NHS in Wales in FY 2018/19, of £27,927 per patient recruited in FY 2018/19 across the relevant commercial and non-commercial studies.

The direct cost savings are estimated to be most significant for commercial health research studies, with the savings estimated in the range of £37,053 per patient recruited in FY 2018/19 compared to £12,412 for non-commercial studies. Aggregating these savings across all studies on the Portfolio in FY 2018/19, we estimate the total value to the NHS of pharmaceutical products provided free of charge was £1.3 million in FY 2018/19.\(^11\)

**Key findings: the added value of the Support & Delivery Service**

To better understand the specific value that the S&D Service adds to the broader health and social care research ecosystem in Wales, we undertook a series of interviews with stakeholders\(^12\) to: obtain evidence and insights relating to the specific benefits and value of health and social care research undertaken in Wales; the role the NHS organisations and the wider S&D Service plays in facilitating such research; and the routes through which the S&D Service generates wider financial, economic and/ or social value. As only a limited number of stakeholders, selected by Health and Care Research Wales, were interviewed, it should be noted that their views may not be fully representative of all stakeholders involved in health and social care research in Wales. The evidence obtained through these interviews is intended to provide a range of insights into the nature of impacts generated by research in Wales and the S&D Service, although the limited number of interviews undertaken means that the findings are indicative only.

The key themes emerging from the 15 stakeholder interviews, in relation to the value added of the S&D Service, are summarised below.

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**Study delivery support:** During our consultation, the majority of stakeholders identified that the S&D Service’s support in study delivery positively impacts on the efficiency, speed and costs with which organisations are able to deliver studies. While stakeholders had a range of views around the specific aspects of support that add value, there were some broad areas highlighted by

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\(^9\) Based on the data received by the S&D Centre, in FY 2018/19 there were 130 site level commercial studies on the Portfolio which recruited at least one patient.

\(^10\) This excludes protocols that did not contain sufficiently complete data to allow us to identify whether a cost saving would occur.

\(^11\) It is important to note that the drug cost savings estimated relate to the trial-long benefit for those patients recruited in FY 2018/19, rather than only the savings associated with the standard treatments that would have been administered to patients during that year. While this may overestimate the annual drug cost savings due to some studies continuing beyond FY 2018/19, as the analysis does not capture any savings associated with studies where patients were recruited prior to FY 2018/19 but were administered free of charge drugs during FY 2018/19, these two effects may offset each other to some extent. Information was not available for us to analyse this.

\(^12\) The stakeholders included sponsor companies, CROs, and NHS organisations, selected by Health and Care Research Wales.
stakeholders in terms of: study set-up; staff capacity; management of resources across Wales; and the implementation of the single costing model\textsuperscript{13} supported by the S&D Service.

— **Wider S&D Service activity:** A number of stakeholders pointed to the positive impacts that arise through the wider support and engagement activity undertaken by the S&D Service, for example, by offering training to researchers and delivery staff, stakeholders felt that the S&D Service adds value to the Welsh research environment. Other areas of S&D Service activity that were considered by some stakeholders to be beneficial include: offering networking opportunities and linking research institutions across the UK; ring-fencing of funding; supporting research approvals and research ethics processes; and Excess Treatment Costs\textsuperscript{14} management.

Stakeholders also provided views on the additionality of the S&D Service’s activity (i.e. how the S&D Service’s activity adds value relative to a hypothetical situation where the S&D Service was not provided and with no alternative in its place). Key points noted are summarised below:

— **Nature of health and care research:** according to three stakeholders, without the S&D Service the nature of the health and care research studies undertaken in Wales would be different. Specifically, they felt there would be more observational and non-commercial studies, and a higher risk of duplication of studies across NHS organisations.

— **Research delivery capacity and capability:** three out of the 15 stakeholders interviewed reported that they believe that without the S&D Service there would be a reduction in the research delivery capacity and capability in Wales.

— **Volume of research undertaken:** approximately a third of the stakeholders interviewed told us that they consider without the S&D Service in place, significantly less health and care research would be undertaken in Wales.

— **Diversification of sites:** if the S&D Service did not exist, two out of the three life sciences industry stakeholders interviewed reported that it would be more difficult, and require more resources, to scope the research sites, resulting in the same sites being selected for each study rather than new sites across Wales being considered.

\textsuperscript{13} One-Wales Contracts & Costings.

\textsuperscript{14} The Support & Delivery Centre manages two centralised budgets to cover Excess Treatment Costs (ETCs) and Support Costs (SCs). Non-commercial studies that are eligible to apply for ETCs & SCs are added to the Health and Care Research Wales Portfolio. See: https://www.healthandcareresearch.gov.wales/excess-treatment-costs-and-support-costs/
Main report
1 About this study

1.1 Scope of this study

In 2016, KPMG undertook a study\textsuperscript{15} to assess the economic impact and value of the National Institute of Health Research (NIHR) Clinical Research Network in England over the financial year ("FY") 2014/15. An update of this study was undertaken for NIHR in 2019 covering the period FY 2016/17 – FY 2018/19.\textsuperscript{16}

Health and Care Research Wales considered there would be significant value in undertaking this exercise across the border in Wales. Therefore, it commissioned KPMG to undertake a similar study, analysing the economic impact and value generated through the health research activity undertaken in Wales.

Health and Care Research Wales is a national virtual organisation in Wales, overseen by the Welsh Government’s Research & Development Division. It consists of several distinct elements of research development and delivery infrastructure. It runs competitive funding schemes, including cross funder initiatives, investment in UK wide programmes and manages resources to promote, support and deliver health and social care research. Its vision is for Wales to be “internationally recognised for excellent health and social care research that has a positive impact on the health, wellbeing and prosperity of the people in Wales”.\textsuperscript{17}

Our study for Health and Care Research Wales assesses the impact and value from the health research activity undertaken by the life sciences industry in Wales, the delivery of health research on the Health and Care Research Wales Portfolio (the “Portfolio”), and the role of the Health and Care Research Wales Support and Delivery Service (the “S&D Service”) in supporting this research. It focuses on the research supported by NHS organisations in Wales, rather than the wider Health and Care Research Wales infrastructure. This also means that only the functions and services undertaken by the S&D Centre relating to its S&D Service functions are included in the study (with Communications, Engagement & Involvement; Training; and Approvals excluded).

Similar to the studies for NIHR, our analysis focuses on the economic impacts generated through the health research activity, rather than the outcomes of the research itself. It focuses on the following areas of impact, agreed with Health and Care Research Wales at the outset of the study:

1. the overall economic contribution associated with the delivery of health research studies on the Portfolio, measured in terms of gross value added\textsuperscript{18} ("GVA") and full time equivalent ("FTE") employment;
2. the monetary value to NHS Wales resulting from delivery of health research, specifically the direct cost savings associated with drugs being provided free of charge by sponsor companies during clinical studies and the commercial income payments to NHS organisations for the delivery of clinical studies; and
3. the wider impacts in the health and social care research market generated by the S&D Service’s activities and the contributions it makes, such as through its provision of study support and its database of study-level data.


\textsuperscript{17} Health and Care Research Wales Aims and Objectives. See: \url{https://www.healthandcareresearch.gov.wales/aims-and-objectives/aims-and-objectives/}

\textsuperscript{18} 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 activity.
Our study does not include any health impacts associated with any new treatment pathways, drugs or medical equipment developed as a result of the health research conducted.\textsuperscript{19} It focuses on research delivery activity, not on research development investment or specific outputs from Health and Care Research Wales funding schemes.

It should be noted that while the scope of the study aligns to the Impact and Value studies undertaken by KPMG for NIHR, this study for Health and Care Research Wales is not intended to provide a direct comparison between the healthcare research and associated economic impacts in England and in Wales. This is due to the differences in scale of activity and research infrastructure across the countries and also as the time frames for the studies do not align. Our analysis in this study relates to the economic impacts generated over a one-year period, FY 2018/19.

The results of this study should be considered within the Welsh context of healthcare research activity, as explained below.

1.2 Context: Health and social care research in Wales

Health and social care R&D activity in the UK benefits from funding provided by the public sector, charity and private sectors.\textsuperscript{20}

Information gathered from the UK Clinical Research Collaboration (the “UKCRC”) Health Research Analysis 2018\textsuperscript{21} shows the volume of funding across the four nations of the UK dedicated to health research. UKCRC provides an estimate of total health-related research performed in UK, by sector (see Figure 2 below). This includes different sources of undefined health research funding not captured in their analysis, including industry funded research, and research taking place in the UK but funded by non-UK organisations.

Figure 2: Estimates (£ billion) of the 2018 UK health-related R&D expenditure by research sector

\begin{figure}
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\includegraphics[width=0.5\textwidth]{figure2.png}
\caption{Source: KPMG analysis of UKCRC 2018 data}
\end{figure}

\textsuperscript{19} We understand form our discussions with Health and Care Research Wales that they intend to conduct a separate study providing case study examples of the health outcomes associated with health and care research supported by the S&D Service in Wales.


According to the UKCRC, in 2018 over 22,500 non-commercial clinical research projects were undertaken in the UK, supported by 146 funding organisations. This non-commercial research alone represented almost £4 billion of investment. Spending on commercial research adds to this although details on the scale of the commercial clinical research projects undertaken in the UK were not provided in the UKCRC 2018 report.

In the UK, each nation has its own government department or agency that is responsible for overseeing, supporting, promoting and funding health and social care research.

- In England, the Department of Health and Social Care ("DHSC") funds health and social care research through the NIHR.
- In Scotland, the Chief Scientist Office, part of the Scottish Government's Health and Social Care Directorate, funds health and social care research working also through NHS Research Scotland.
- In Northern Ireland, the Health and Social Care Public Health Agency HSC R&D Division funds health and social care research.
- In Wales, the Health and Social Services group's Research & Development Division (RDD) funds health and social care research through Health and Care Research Wales.

As explained above, Health and Care Research Wales' vision is for Wales to be "internationally recognised for excellent health and social care research that has a positive impact on the health, wellbeing and prosperity of the people in Wales". In order to achieve this vision, the stated aims referred to in the 2015-2020 Health and Care Research Wales strategy are:

- ensure public involvement and engagement is central to what Health and Care Research Wales does and is visible in all elements of it;
- ensure its work is aligned to Welsh Government policy and has real impact;
- fully integrate its infrastructure and programmes;
- invest in areas in which Wales excels and is unique;
- increase capacity in health and social care research in Wales; and
- develop ways of working that ensure excellent delivery and maximise the use of resources.

In 2018/19, the Health and Care Research Wales budget was £42.5m. Of this, around £16m was spent on local support and delivery across the Health Boards and Trusts in Wales. In addition, around £10.6m was spent on research development infrastructure, including national research centres and units and national research support groups, £3.82m on a Support and Delivery Centre, and around £12m on research programmes. Research programmes spend includes Health and Care Research Wales’s own funding schemes as well as partnerships and contributions to cross-funder initiatives and UK-wide programmes.

Part of the funding Health and Care Research Wales receives from the Welsh Government is allocated to the Health and Care Research Wales S&D Service. This is a Wales-wide service which provides a range of support functions to sponsors, researchers and the public and aims to ensure that support is in place, at the national (via the S&D Centre) and local level (via NHS R&D departments), to set up, and deliver health and social care research studies across Wales. This includes the provision

of advice and funding for the promotion and delivery of both commercial26 and non-commercial27 research in Wales.28 Its vision is to realise a ‘One Wales Seamless Service’ for supporting and delivering high quality health and social care research and its mission is “to facilitate health and social care research that will improve the health and well-being of people in Wales by providing an effective and efficient joined-up centralised and local service”.29

The S&D Service is delivered by a coordinated network of the local NHS R&D departments in Wales and the national S&D Centre. The scope of the S&D Service aligns to the research pathways and seeks to provide support for feasibility design and assessment, regulatory approvals, and study recruitment support.30 Its infrastructure exists within an extensive health and care research ecosystem in Wales, involving a large number of stakeholders. Table A1 in the Appendix set out the roles of different stakeholder groupings in health and care research activity in Wales.

One of the functions of the S&D Service is to manage a comprehensive research directory of the health and social care research being undertaken in Wales. The Portfolio is a subset of the research directory consisting of commercial and non-commercial research, and while all commercial studies undertaken in Wales are on the Portfolio, only "high-quality non-commercial research" is included.31

According to the Portfolio data received from the S&D Centre, in FY 2018/19 there were 746 studies on the Portfolio, which recruited 20,755 participants. This is an increase in both the number of studies and recruits compared to prior years. Over the period FYs 2015/16-2018/19 the total number of studies on the Portfolio had increased by 10%, while the number of participants recruited had increased by 46%. Of the studies on the Portfolio in FY 2018/19, approximately 76% were non-commercial, and approximately 96% of total study participants were recruited onto these non-commercial studies.

26 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.
27 Non-commercial studies are initiated by non-commercial researchers. These studies are usually paid for with grant funding from charities, Government or other not-for-profit organisations. However, the category of non-commercial clinical research also includes ‘investigator-initiated trials’ (IITs). These are sponsored by an NHS Organisation or university (which, therefore, retain the intellectual property rights for the study) but which receive funding or free drugs from a commercial company.
31 Health and Care Research 2018, Classification on the Health and Care Research Wales Directory and criteria governing eligibility for support, received by the S&D Centre in January 2020.
In terms of trends in the commercial clinical research activity on the Portfolio, over the four years there has been a slight decrease in the number of studies and recruits.

Figure 3 illustrates that the nature of commercial studies has remained stable through the four years, with approximately 76% of commercial studies being interventional in FY 2018/19. However, Figure 3 shows this is not the case for recruits onto commercial studies. While in FYs 2016/17-2017/18 the number of recruits onto observational studies was almost double the number of participants recruited onto interventional studies, in FY 2018/19 the number of recruits onto interventional commercial studies was significantly higher than observational commercial recruits. The slight decrease in number of interventional commercial studies on the Portfolio, together with an increase in recruits onto interventional commercial studies, seems to suggest the Portfolio now consists of fewer interventional commercial studies which recruit a greater number of patients.

Figure 4: Non-commercial health studies and recruits on the Portfolio
Figure 4 shows that over the last four years there was an increase in the number of non-commercial studies and recruits on the Portfolio. In FY 2018/19 the non-commercial portfolio was made up of slightly more observational studies than interventional, and this difference is more marked when looking at numbers of recruits.

**Figure 5: Non-commercial public health studies and patients on the Portfolio**

![Graph showing number of recruiting studies and number of recruits over four financial years.](source: KPMG analysis of Health and Care Research Wales data)

In terms of non-commercial public health research, Figure 5 shows that over the four year period there was an increase in the number of studies and participants recruited, and in FY 2018/19 there were seven public health studies on the Portfolio which recruited 1,567 participants. While five of the seven studies were observational, almost 70% of the participants were recruited onto interventional studies, a significant increase compared to prior years. This was specifically driven by one interventional public health study which recruited 1,071 participants on its own.
2 The framework for assessing the impact and value of health research

In this Section we detail our framework for assessing the economic impact and value generated through the health research activity of the life science industry in Wales, the delivery of health research on the Portfolio, and the role of the S&D Service in supporting this research. Specifically, this Section includes:

— the high-level approach taken in our quantified analysis of economic impacts and monetary value to NHS organisations;
— the approach taken to our stakeholder engagement;
— sources of data used; and
— the limitations of our analysis.

Our impact assessment has been conducted in line with the approach used in our 2016 and 2019 reports for the NIHR, and in accordance with the UK Government recognised appraisal methodologies set out in HM Treasury’s Green Book. Further details of our analytical approach are included in the Technical Appendix.

2.1 Approach to estimating the economic contribution of the health research activity

As explained in Section 1.1, the study includes an assessment of the overall economic contribution measured in terms of GVA and employment, associated with the following health research activities in Wales:

— **S&D Centre**: impacts generated by the S&D Centre - part of the S&D Service - which supports both commercial and non-commercial health and social care research.

— **Non-commercial research**: impacts generated by universities and principal investigators associated with their initiation of non-commercial health research funded by charities and other non-commercial funders; and by the research delivery staff within NHS R&D departments, funded by the S&D Service, through their delivery of non-commercial health research on the Portfolio, funded by charities and other non-commercial funders.

— **Commercial research**: impacts generated by life sciences industry sponsor companies and CROs associated with their undertaking health research activity in Wales and initiating and funding commercial health research; and by NHS organisations and other care providers associated with their delivery of commercial health research on the Portfolio, funded by the life sciences industry.

Approach to estimating the GVA and employment impacts

In our analysis, one of the measures of economic contribution used to capture the impact of research activity supported by NHS organisations in Wales is the total GVA contribution.
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 activity.34

The health research activity supported by NHS Wales directly adds GVA to the Welsh and, more widely, to the UK economy through the employment it generates within NHS organisations35 and other care providers, universities, sponsor companies, CROs and the S&D Centre, and through the inputs (e.g. products and services) used to deliver the research activity. We estimate the economic impact generated through each of these areas.

Our analysis also captures the employment generated as a result of the health research activity undertaken by the life sciences industry in Wales and the delivery of health research on the Portfolio.

The GVA and employment contribution of health research activity in Wales is generated via three main routes:

— **Direct**: the first-round effects of the activity of those directly involved in the initiation and delivery of health research.

— **Indirect**: the second-round effects through the activity and output supported in the supply chain. To initiate and deliver health research studies a range of products and services are required which, for example, may include supplies of medical equipment and provision of management information systems in the case of NHS organisations and care providers. This supply chain procurement generates economic activity both at the direct supplier as well as through each of their individual supply chains, thereby multiplying the economic activity through the economy.

— **Induced**: the multiplier effects that arise as a result of direct and indirect employees involved in the delivery of research activity spending a proportion of their associated wages in the UK economy. This spending generates additional economic activity for businesses from which these employees buy goods and services and through those businesses’ wider supply chains.

The direct GVA impacts are measured using the income approach to calculation of GVA.37 The indirect and induced GVA and employment impacts are assessed based on an input-output modelling approach. Our analysis uses the Office for National Statistics (“ONS”) input-output tables and the Type I and Type II multipliers derived from these.38 The input-output tables show, in matrix form, the inter-linkages between sectors of the economy in terms of the value of goods and services (inputs) that are required to produce each unit of the output in given sectors of the economy.

In our analysis we report employment in full-time equivalent (FTE) terms. This adjusts part time or temporary staff into an annual full-time equivalent based on the proportion of full-time hours worked over a year.

### 2.2 Approach to estimating the monetary value to the NHS of health research activity

As a result of supporting industry-sponsored health research studies on the Portfolio, the NHS secures additional revenues and also benefits from direct cost savings. These impacts arise through the

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35 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 organisations and other care providers.

36 We estimate indirect and induced GVA and employment impacts using sector specific GVA and employment multipliers sourced from the ONS and Scottish Government. 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.

37 This defines GVA as follows: GVA=Net pre-tax profit+Compensation of Employees+Depreciation+Amortisation

payments made by sponsor companies and CROs to NHS organisations for industry-sponsored studies. Direct cost savings to the NHS also arise as a result of the drugs trialled being, in some cases, provided free by sponsor companies in place of the standard treatment which otherwise would be funded by the NHS. We quantify these impacts as part of this study.

**Approach to estimating payments to NHS organisations for commercial health research**

Health research is often commissioned by a sponsor company. This is referred to as commercial research. In such studies, NHS research sites receive payments from the industry sponsor companies to fully cover the costs incurred in the process of delivering health research. These payments, referred to as ‘per patient payments’, can represent a significant income stream for the NHS organisations. Whilst this income stream offsets costs incurred for the delivery of health research, it enables sites to undertake more research, without there being an opportunity cost to delivery of other NHS services. As well as covering the direct costs, the payments include a ‘capacity building’ element, set at 20% of costs, which is intended to be used to build sustainable research and innovation capacity to the benefit of all research partners. The payments also include an allowance to cover the indirect costs incurred by an organisation in running the research activity (set at 70% of direct costs).

To estimate these payments, we collected data directly from the ten NHS organisations that deliver research in Wales. We obtained payment data, on a per patient recruited on to studies basis, covering a total of 119 site level payments for commercial studies on the Portfolio. This data was used to understand both the overall level of payments made and to provide further insights into how these payments vary dependent on the type of health research study delivered by the NHS.

As well as payments for commercial studies, in some cases NHS organisations receive some industry funding for IITs. As part of our study we requested NHS organisations provide payments relating to IITs to include in our analysis.

**Approach to estimating NHS cost savings associated with conducting health research**

Commercial health research studies that test drugs provide NHS organisations and patients with free access to these drugs and treatments. This means the NHS organisations delivering the research do 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.

As explained in our report to the NIHR (2019), there will be instances where commercial health research studies deliver value beyond this cost saving. Some studies provide NHS organisations and patients with free access to more expensive drugs that may be licensed in other instances but are now being trialled in a new disease-area. In the absence of the study, patients would not have access to these more expensive and potentially effective drugs. In this case, the value to the NHS stretches beyond the cost saving of standard treatment to the additional value of using these more expensive trial drugs.

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40 These costs include heating, lighting, building maintenance, security, finance, general admin, human resources, corporate management and all other resources which allow the organisation to function. Indirect costs are applied to direct staff costs only.
41 Out of the ten NHS organisations, only seven undertook commercial studies in FY 2018/19.
42 Based on the data received by the S&D Centre, in FY 2018/19 there were 130 site level commercial studies on the Portfolio which recruited at least one patient.
43 These are trials that are sponsored by an NHS organisation or university, and therefore classified as non-commercial, but which received funding or free drugs for use in the trial from industry.
Through consultation with the S&D Centre we understand that in some instances non-commercial health research studies that test drugs also provide NHS organisations and patients with free access to drugs and treatments. In the same way the free drugs are provided for commercial studies, the free access to drugs and treatments for non-commercial studies will also generate some savings for the NHS.

To estimate the costs savings in instances where the trial drug, provided free of charge, replaces the standard treatment, we obtained data and information associated with the Portfolio of commercial, interventional studies which were undertaken in FY 2018/19. The ten NHS organisations delivering relevant studies also provided information on the non-commercial studies undertaken at their site where drugs were provided free of charge. Full details of the approach taken are reported in the Technical Appendix A1.3.2.

Due to data limitations, our analysis is restricted to the pharmaceutical cost savings in the cases where Health and Care Research Wales was able to identify that the trial drugs were provided free of charge and replace the standard treatment. We note that there would also be a cost saving for the NHS associated with the provision and use of medical devices in equivalent medical device studies, however due to a lack of available data we were not able to quantify these savings in the study. As a result of this our estimates of the direct cost savings to the NHS associated with the delivery of health research may underestimate the full scope of potential savings.

2.3 Approach to assessing added value

The impacts quantified in this report represent the gross impact and value of the research activity within the scope of our study. That is, it does not account for the extent to which the research and its associated economic impacts would occur in the absence of the Health and Care Research Wales S&D Service. For this we need to consider the additionality. Additionality considers the net, rather than gross, impacts after making allowances for what would have happened in the absence of Government support. As set out in HM Treasury’s Green Book, consideration of additionality is important when conducting economic appraisals.

However, the additionality of the S&D Service within the health and social care research ecosystem is not easily quantified. Directly capturing what Welsh health and social care research activity would look like in the absence of the S&D Service’s support is not possible within the scope of the study as there is no robust counterfactual against which to compare impact. Therefore, our analysis of the added value (additionality) draws primarily on qualitative evidence, obtained through stakeholder consultation, of the specific role that the S&D Service plays in the health and social care research ecosystem in Wales.

Over the period March to May 2020 we completed semi-structured telephone interviews with 15 stakeholders including sponsor companies, CROs, and NHS organisations, selected by Health and Care Research Wales. As part of the interviews we sought views on:

— the nature of the stakeholder’s role in research and the extent to which they had engaged with the S&D Service and used its services;
— the ways in which the S&D Service impacts the stakeholders’ research activities and the nature of these impacts;
— how the stakeholder’s research activity in Wales would differ if the S&D Service did not exist;
— how the overall research landscape in Wales would differ if the S&D Service did not exist;
— the ways in which the S&D Service could deliver more value going forward.

Stakeholders were selected with the aim of obtaining views from a cross-section of stakeholders, for example selecting stakeholders involved in different aspects of research and from organisations of different sizes. All stakeholders had some prior engagement with the S&D Service.
The semi-structured nature of the interviews enabled us to explore specific responses by stakeholders to the issues listed above in more depth where required, in particular where we identified any common themes emerging among stakeholders that we wanted to test with wider stakeholders.

2.4 Data sources and limitations

Data sources

To conduct our analysis, using the approaches detailed above and in the Technical Appendix, we relied on a range of primary and secondary data and information sources. These are summarised below:

— financial and management data (e.g. payroll costs and FTE figures associated with the S&D Service), provided by the S&D Centre;
— information on the health and social care research studies on the Portfolio (e.g. number of recruits, therapeutic area, and type of research) provided by the S&D Centre;
— financial data relating to income for commercial studies, provided by NHS organisations;
— information and insights gathered through interviews with sponsor companies, CROs, and NHS stakeholders;
— publicly available data, including from the ONS, Association of British Pharmaceutical Industry (the “ABPI”); and the UKCRC; and
— data from drug databases including NICE BNF and emc databases.

A description of the available data and approach used for the different areas of the analysis is set out in Table A2 in the Appendix.

Data limitations

Whilst we sought to obtain the most appropriate and up to date data to inform our analysis, the following limitations apply and should be considered when interpreting the results:

1 The ONS data on R&D expenditure in the pharmaceutical sector, and UKCRC data on grant funding to health research activity relate to calendar year rather than financial year, therefore it does not directly relate to the same time period as the rest of the analysis. Nonetheless, as the data does not fluctuate significantly year on year, we consider the estimates to provide a reasonable proxy for the equivalent for the financial year.

2 As part of our analysis of economic impacts generated by commercial health research activity on the Portfolio, we use ONS data on R&D expenditure in the pharmaceutical sector in Wales in 2018. While we use this expenditure data as a proxy of the investment of sponsor companies and CROs to initiate and fund commercial research in Wales, all that spending may not be ultimately associated with studies which are then conducted in Wales. Due to this, our estimation of the economic impact generated by commercial health research activity on the Portfolio in FY 2018/19 may be overestimated.

3 The latest data on the proportion of pharmaceutical R&D that is spent on clinical research, sourced from ABPI, is from 2016 and is a global figure. This data is used in the estimation of GVA and employment generated by the commercial clinical research undertaken by sponsor companies. As it is unclear how the proportion of pharmaceutical R&D that is spent on clinical research may have

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46 NICE BNF, See: https://bnf.nice.org.uk/
47 emc, See: https://www.medicines.org.uk/emc
changed since 2016, it is not clear whether using the 2016 data may result in our analysis either over- or under-estimating the actual impacts in 2018/19.

4 Data received from NHS organisations on staff hours and costs associated with commercial studies open to recruitment in FY 2018/19 differed in terms of completeness and granularity across NHS organisations:

— Four NHS organisations provided study-level data (directly extracted from the costing templates) on per-patient staff costs and hours dedicated to all commercial studies undertaken at their NHS organisation in FY 2018/19.

— Three NHS organisations provided study-level data (directly extracted from the costing templates) on per-patient staff costs and hours dedicated to the majority of commercial studies undertaken (57%, 90%, and 95% respectively). This data had to be scaled up, based on the number of patients recruited, to estimate the total staff costs and hours dedicated to commercial studies undertaken in FY 2018/19.

— One NHS organisation provided study-level data (directly extracted from the costing templates) on per-patient staff costs but was only able to provide an estimate for total staff hours dedicated to commercial studies. Conversely another NHS organisation provided study-level data (directly extracted from the costing templates) on per-patient staff hours but was only able to provide an estimate for total staff costs.

As a result of these differences in data and the estimation approaches used for staff hours and costs, the analysis based on this data may over- or under-estimate the impacts.

5 Data received from one NHS organisation on its per-patient payments received from sponsor companies and CROs for the delivery of commercial studies on the Portfolio in FY 2018/19 covered total study costs, rather than only per-patient budgets. Total study costs include some areas of cost not required for our analysis. While we were able to adjust the figures to remove set-up fees, it was not possible to remove any additional fees such as additional itemised costs (AIC) and pharmacy fees. As a result of this, our estimates of the total payments to NHS organisations in FY 2018/19 may be slightly overestimated.

6 Due to a lack of available data from public sources on the cost of standard treatments using medical devices on a per patient basis, our analysis does not include any cost savings associated with trial medical devices being provided free of charge as part of health and care research studies. As a result of this limitation, our estimates of the direct cost savings to the NHS associated with conducting research may underestimate the full scope of potential savings.
3 The economic contribution of health research activity supported by NHS organisations in Wales

In this Section, we present the results of our analysis relating to:

— the GVA and employment impacts associated with commercial and non-commercial health research activities supported by NHS organisations in Wales; and
— the commercial income payments to the NHS organisations for the delivery of health research studies and costs savings to the NHS associated with drugs being provided free of charge by sponsor companies.

3.1 GVA and employment impacts

3.1.1 Summary of total GVA and employment impacts

As explained in Section 2.1, in our analysis we estimate the UK economic contribution in FY 2018/19 of the health research activity undertaken by the life sciences industry in Wales, the delivery of health research on the Portfolio, and the activities of the S&D Centre, measured in terms of direct, indirect and induced GVA and employment. This includes the economic impacts associated with the research supported by NHS Wales across the Portfolio of studies that were initiated and delivered by a range of research stakeholders including NHS organisations, charities, sponsor companies, CROs and universities.

In total, we estimate that commercial and non-commercial health research activity relating to the studies on the Portfolio generated a total of £93 million in GVA and supported approximately 1,600 FTE jobs in the UK in FY 2018/19.
The total GVA impact in FY 2018/19 comprises an estimated:

- £53 million in GVA and 950 jobs associated with non-commercial research activity initiated by charities and universities, and undertaken by NHS organisations;
- £36 million in GVA and 600 jobs associated with commercial health research activity undertaken by sponsor companies and CROs, and commercial research activity funded by sponsor companies and CROs and delivered by NHS organisations; and
- £4 million in GVA and 50 jobs associated with the S&D Centre’s activities relating to its S&D Service functions, including its support for both commercial and non-commercial research.

Further details on the economic contributions generated through these three areas of the S&D Service-supported research activity are provided in Sections 3.1.2, 3.1.3, and 3.1.4 below, while specific details on the approach used are provided in the Technical Appendix A1.1.

3.1.2 The economic impact of non-commercial health research activity supported by NHS organisations in Wales

Summary of total economic impact generated by non-commercial health research

NHS organisations in Wales support a range of non-commercial research activity.49 In FY 2018/19 there were 564 non-commercial studies on the Portfolio, which recruited a total of 19,918 patients. The non-commercial research activity on the Portfolio includes the health research activity that is funded by charities, research councils and Government. In general, this health research activity is initiated by universities, academic clinical trials units, NHS principal investigators or in some cases charities themselves. However, its delivery tends to be carried out by research delivery staff within NHS R&D departments, funded through the S&D Service. As detailed in Section 2.1, our analysis estimates the economic impact generated through both channels.

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49 In FY 2018/19 there were 564 non-commercial studies on the Portfolio supported by 10 sites, which recruited a total of 19,918 patients.
Our analysis shows that in FY 2018/19 the total economic impact generated by this non-commercial health research activity on the Portfolio amounted to an estimated £53 million in terms of GVA. It also supported approximately 950 FTE jobs. The breakdown of these contributions by area of activity are detailed below.

**Economic impact generated by non-commercial grant funded health research activity**

Of the £53 million of all non-commercial health research activity on the Portfolio in FY 2018/19, we estimate that £33 million of GVA was generated from health research activity initiated by universities and NHS principal investigators, funded by non-commercial grants, and approximately 400 FTE jobs were supported. The estimated GVA and employment contribution from non-commercial health research activities on the Portfolio and funded by non-commercial grants in FY 2018/19 is shown in Figure 7 below.

**Figure 7: Estimated GVA and employment contribution of non-commercial health research activity on the Portfolio funded by non-commercial grants, FY 2018/19**

![Graph showing estimated GVA and employment contribution](image)

Source: KPMG analysis

**Economic impact generated by non-commercial health research activity on the Portfolio delivered by NHS organisations**

Of the total estimated economic contribution of all non-commercial health research activity on the Portfolio in FY 2018/19, our analysis shows that approximately £20 million of GVA and 550 FTEs was generated from non-commercial health research activity delivered by the research delivery staff at NHS organisations.

**Table 1: GVA and employment impact of non-commercial health research activity delivered by NHS organisations, FY 2018/19**

<table>
<thead>
<tr>
<th>Direct impact</th>
<th>Indirect impact</th>
<th>Induced impact</th>
<th>Total impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>GVA (£ Million)</td>
<td>£13.9</td>
<td>£1.3</td>
<td>£4.6</td>
</tr>
<tr>
<td>Employment</td>
<td>409</td>
<td>41</td>
<td>84</td>
</tr>
</tbody>
</table>

Source: KPMG analysis
This analysis shows that in FY 2018/19 health research initiation activities for non-commercial studies (e.g. study design) carried out by universities and other non-commercial partners in Wales generated larger economic impacts in the UK than the delivery of studies on the Portfolio by NHS organisations (see results in Figure 7 and Table 1).

3.1.3 The economic impact of commercial health research activity supported by NHS organisations in Wales

Summary of total economic impact generated by commercial health research activity

NHS organisations in Wales also support the initiation and delivery of commercial health research, including commercial health research activity conducted within sponsor companies and CROs in Wales, as well as commercial research activity undertaken by NHS organisations.

In FY 2018/19 there were 182 commercial studies on the Portfolio, which recruited a total of 837 patients. We estimate that, collectively, the commercial research on the Portfolio generated £36 million in GVA and supported 600 FTE jobs in FY 2018/19. We detail below the composition of these economic contributions based on the type of organisation delivering the commercial research activity.

Economic impact generated by commercial health research activity undertaken by sponsor companies

Of the total estimated economic contribution of the commercial studies on the Portfolio in FY 2018/19, our analysis shows that the majority of the total £36 million of GVA generated and 600 FTEs was generated by health research activity within sponsor companies and CROs in Wales.

Our analysis shows that the economic contribution of health research activity conducted by sponsor companies and CROs, in terms of GVA, in FY 2018/19 was an estimated £34 million, and approximately 550 FTE jobs were supported. Figure 8 below shows the split of the GVA and employment impacts by direct, indirect and induced impacts.

As highlighted in Section 2.4, however, the spending associated with health research activity conducted by sponsor companies and CROs in Wales may not be ultimately associated with studies which are then conducted in Wales and supported by NHS organisations. Our results may therefore overestimate the economic impact generated by commercial research activity supported by NHS Wales undertaken within sponsor companies and CROs.
Economic impact generated by commercial health research activity undertaken by NHS organisations

Commercial health research activity is not undertaken exclusively by sponsor companies and CROs. NHS organisations also participate in commercial research activity by delivering clinical studies for the sponsor companies and CROs. Sponsor companies fund this research by providing payments to NHS organisations based on the study design and the number of patients recruited onto the study.

We estimate that commercial health research activity delivered by NHS organisations, and included on the Portfolio, generated a total of £1.7 million in GVA and 30 FTE jobs in the UK in FY 2018/19. Table 2 below shows the split of these GVA and employment impacts by direct, indirect and induced impacts.

Table 2: GVA and employment impact of commercial health research activity undertaken by NHS organisations, FY 2018/19

<table>
<thead>
<tr>
<th></th>
<th>Direct impact</th>
<th>Indirect impact</th>
<th>Induced impact</th>
<th>Total impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>GVA (£ Million)</td>
<td>1.2</td>
<td>0.1</td>
<td>0.4</td>
<td>1.7</td>
</tr>
<tr>
<td>Employment</td>
<td>23</td>
<td>2</td>
<td>5</td>
<td>30</td>
</tr>
</tbody>
</table>

Source: KPMG analysis

Our analysis shows that the GVA and employment impact associated with NHS organisations’ delivery of non-commercial health research on the Portfolio was significantly higher in FY 2018/19 than the impact associated with the commercial studies on the Portfolio. There may be a number of reasons why this was the case including the number of studies, nature of the studies and the scale of the studies, as measured by the number of patients recruited on to them. In FY 2018/19 there was a significantly higher number of non-commercial studies on the Portfolio than commercial studies, and on average non-commercial studies had an additional 30 recruits compared to commercial studies. However, we note that a larger proportion of commercial studies were interventional (76% in commercial studies vs 44% in non-commercial studies) and we understand from Health and Care
Research Wales that the cost and complexity of delivering interventional trials is, in general, higher than for observational studies. If that is the case, this would also affect the GVA and employment impacts generated by different types of studies.

### 3.1.4 The economic impact of the activity of the Support & Delivery Centre

The S&D Centre undertakes a range of activities to support the delivery of health and social care research in Wales. In FY 2018/19, the S&D Centre supported the set-up and oversight of delivery of 746 studies with 20,755 patients recruited on to these studies.

In total, in FY 2018/19, we estimate that through its own activities the S&D Centre generated approximately £4 million of GVA and supported 50 FTE jobs relating to its S&D Service functions. The breakdown of these impacts is shown in Figure 9.

**Figure 9: Economic impact of the S&D Centre activity, FY 2018/19**

![Figure 9: Economic impact of the S&D Centre activity, FY 2018/19](image)

**Source:** KPMG analysis

### 3.2 Monetary value to NHS organisations of health research activity

Through delivering health research, NHS organisations make a monetary gain, both through the additional revenues generated through payments for conducting the research as well as through the savings made on standard treatments where the drugs being trialled as an alternative are provided free of charge. Within the scope of the study we have assessed the value of these additional revenues and direct cost savings to understand the monetary impacts associated with the health research on the Portfolio that is delivered by NHS organisations. These impacts are additional to the economic impacts estimated in Section 3.1.

In our analysis we estimate the monetary value across all relevant commercial studies on the Portfolio, and also across those studies that are initiated by non-commercial partners, but sponsored by the life sciences industry (categorised by Health and Care Research Wales as non-commercial studies). These non-commercial studies have monetary value to NHS organisations as the sponsor companies contribute payments and drugs in the same way as for commercial studies.

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50 Known as industry-sponsored Investigator Initiated Trials.
As our analysis in this Section shows, the monetary impacts can be sizeable for NHS organisations. For the health research on the Portfolio in FY 2018/19 we estimate that the total monetary value to NHS organisations for delivering the commercial research was approximately £8.7 million, comprised of approximately £7.4 million of commercial income relating to payments for commercial studies on the Portfolio and approximately £1.3 million of direct pharmaceutical cost savings across the commercial and non-commercial Portfolio in FY 2018/19.

Details of this analysis and a breakdown of results are provided below.

### 3.2.1 Payments to NHS organisations

When conducting commercial clinical studies, secondary care providers (such as NHS organisations) and primary care providers (such as GP practices) receive income for delivering commercial research. This income covers the costs of staff time for undertaking the study, indirect costs (such as overheads) and a capacity building element, set at 20% of costs, which is ring fenced to build sustainable research and innovation capacity.51

Therefore, whilst some elements of the income represent compensation for the costs involved in the delivery of health research, the capacity building element is intended to enable sites to build sustainable research capacity to the benefit of all research partners. Furthermore, by receiving direct payment for the health research they deliver, NHS organisations and other care providers can undertake more health research without it generating an opportunity cost in relation to provision of NHS services.

Out of the ten NHS organisations delivering health research in Wales, data provided to us showed that in FY 2018/19 seven NHS organisations in Wales received patient payments for delivering commercial health research. In total, the per patient payments received by NHS organisations for conducting commercial clinical studies on the Portfolio in Wales in FY 2018/19, was an estimated £7.4 million. On a per-patient basis, our analysis estimates that the average per patient payment in FY 2018/19 was £11,873.

There was, however, significant variation in per patient payment values across the studies conducted by the seven NHS organisations. Table 3 below shows the distribution of per-patient payment data. This analysis shows that in FY 2018/19 the median per patient payment value (£5,255) was considerably lower than the mean value (£11,873). This is because there were a small number of study sites for which very high per patient payments were made, skewing the mean value upwards. The analysis shows that the maximum per patient payment received was over £90,00052. However, payments for the majority of studies were considerably lower.

### Table 3: Distribution of per-patient payments, FY 2018/19

<table>
<thead>
<tr>
<th>Number of studies for which patient payments were received</th>
<th>Mean value of per-patient payments</th>
<th>Median value of per-patient payments</th>
<th>Minimum value of per-patient payments</th>
<th>Maximum value of per-patient payments</th>
<th>Standard deviation of value of per-patient payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>119</td>
<td>£11,873</td>
<td>£5,255</td>
<td>£74</td>
<td>£91,531</td>
<td>£18,209</td>
</tr>
</tbody>
</table>

Source: KPMG analysis

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52 It should be noted that this study had significant indirect and capacity building costs associated with it. Also, the data relating to this commercial study was provided by an NHS organisation that was only able to provide total study costs. Therefore, this payment may also include pharmacy fees and additional itemised costs.
To further understand the distribution of per patient payments across studies we also analysed the distribution of payments across the specialties the research was focused on. This helped us to understand if, and how, commercial revenue differs across therapeutic areas.

As illustrated in Figure 10 in Wales in FY 2018/19 studies in the ‘Neurological Disorders’ therapeutic area are estimated to have received the highest average per patient payments of approximately £23,000. Clinical studies in ‘Anaesthesia, Perioperative Medicine and Pain Management’ instead were the ones which received the lowest average per patient payments of approximately £74 per patient. Health and Care Research Wales informed us, however, that while this was the position in FY2018/19, this may not always be the case and average per-patient payments across therapeutic areas may differ each year dependent on the specific studies being undertaken.

Figure 10: Average per-patient payments across therapeutic areas, FY 2018/19

Source: KPMG analysis

### 3.2.2 The direct pharmaceutical cost savings to the NHS

In addition to the commercial revenues NHS organisations receive for conducting commercial health research studies, there are other monetary impacts of undertaking health research activity. Specifically, there are some direct cost savings to NHS organisations. These savings arise where the sponsor companies provide drugs free of charge for clinical studies and these replace the standard treatments that would otherwise have been administered and paid for by the NHS organisations.

While our analysis estimates the direct costs savings to the NHS from the avoided cost of the standard treatments where free trial drugs are provided, we note that commercial sponsor companies may, to some extent, recoup the costs of providing these products from future sales of the trial product or from the sale of other products to the NHS. However, we were unable to assess this as part of this study.

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53 This is in line with the 30 therapeutic areas of the NIHR and Health and Care Research Wales.
due to data availability. Therefore, our analysis focuses on the direct savings from the standard treatments only.

Based on our analysis we estimate that drugs were provided free of charge, in place of the standard treatment, in around 24% of commercial studies on the Portfolio, and 6% of non-commercial studies on the Portfolio54.

Our analysis estimates an average pharmaceutical cost saving to the NHS in FY 2018/19, of £27,927 per patient recruited in FY 2018/19 across the relevant commercial and non-commercial studies. The direct cost savings are estimated to be most significant for commercial health research studies, with the savings estimated in the range of £37,053 per patient recruited in FY 2018/19 compared to £12,412 for non-commercial studies.

There is, however, significant variation in drug cost savings across the studies analysed. As can be seen from Table 4, the median value for drug cost savings across relevant studies is below the mean value. This indicates that the savings for most of the studies are at the lower end of the range with the mean value being pulled upwards by a small number of studies with very high drug cost savings.

<table>
<thead>
<tr>
<th>Type of study</th>
<th>Number of payments</th>
<th>Mean value of per-patient drug cost saving</th>
<th>Median value of per-patient drug cost saving</th>
<th>Minimum value of per-patient drug cost saving</th>
<th>Maximum value of per-patient drug cost saving</th>
<th>Standard deviation of value of per-patient drug cost saving</th>
</tr>
</thead>
<tbody>
<tr>
<td>All studies</td>
<td>27</td>
<td>£27,927</td>
<td>£7,083</td>
<td>£17</td>
<td>£211,200</td>
<td>£45,896</td>
</tr>
<tr>
<td>Commercial</td>
<td>17</td>
<td>£37,053</td>
<td>£10,718</td>
<td>£17</td>
<td>£211,200</td>
<td>£54,579</td>
</tr>
<tr>
<td>Non-commercial</td>
<td>10</td>
<td>£12,412</td>
<td>£5,726</td>
<td>£1,139</td>
<td>£55,250</td>
<td>£15,524</td>
</tr>
</tbody>
</table>

Source: KPMG analysis

Based on the per patient drug cost savings for each relevant study on the Portfolio and the number of patients recruited on to those studies in FY 2018/19, we estimate that the total direct cost saving attributable to the provision of free of charge drugs for use in clinical studies was £1.3 million.55

As shown in Figure 11 the large majority of the drug cost savings were associated with commercial studies (an estimated £1.2 million). The cost savings to the NHS from non-commercial studies were an £0.1 million in FY 2018/19. This is likely to be a result, at least in part, of the higher number of patients recruited on to commercial studies in FY 2018/19 where there was a drug cost saving (38 patients compared to 11 patients recruited on to non-commercial studies).

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54 The percentages are estimated based on the number of studies on the Portfolio which recruited at least one patient in FY 2018/19.
55 The cost savings per study were estimated by multiplying the drug cost saving per patient to the number of patients recruited in the study in FY 2018/19.
It is important to note that the drug cost savings estimated relate to the savings made for patients recruited on to Portfolio studies in FY 2018/19 over the full duration of the study (which in some cases extended beyond FY 2018/19), rather than only the savings associated with the standard treatments that would have been administered to patients during FY 2018/19. While this may overestimate the annual drug cost savings due to some studies continuing beyond FY 2018/19, since the analysis does not capture any savings associated with studies where patients were recruited prior to FY 2018/19 but were administered free of charge drugs during FY 2018/19, these two effects may offset each other to some extent. Information was not available to analyse this.

Full details of our approach to estimating these cost savings are reported in the Technical Appendix A1.3.2.
4  The added value of the Support & Delivery Service

To better understand the specific value of research in Wales, and also the value that the Health and Care Research Wales S&D Service adds to the broader health and social care research ecosystem, we undertook a series of interviews with stakeholders. Through this consultation we sought to obtain evidence and insights relating to the specific benefits and value of health and social care research undertaken in Wales, the role the NHS organisations and the wider S&D Service plays in facilitating such research, and the routes through which the S&D Service generates wider financial, economic and/or social value. In particular, given that the Portfolio of health and care research forms only one part of the overall health and care research landscape, we sought stakeholder insights on the additionality of the S&D Service’s activity — that is how the S&D Service’s activity adds value beyond what would otherwise be delivered in terms of health and care research activity in Wales in its absence.

Due to the relatively small number of stakeholders spoken to, and the process for selecting these, it should be noted that the views and insights gathered through the stakeholder interviews may not be representative of the views of all health and social care research stakeholders in Wales. Due to the broad range of views shared during the interviews, our findings below capture the key themes that emerged across the interviews rather than each individual point raised. The evidence obtained through these interviews is intended to provide a range of insights into the nature of impacts generated by research in Wales and the S&D Service and is indicative only.

4.1 The Welsh research environment

Our stakeholder interviews highlighted that there are specific characteristics of the Welsh environment which stakeholders consider make it an attractive location for undertaking health and social care research.

The benefits of the Welsh research environment

Approximately half of the stakeholders interviewed raised common themes in relation to particular attributes of the Welsh research environment which differentiate it from the other countries of the UK. They suggested that these attributes make Wales an attractive location to undertake research, as they contribute toward increasing the efficiency, scope and the benefits of the research activity undertaken by researchers. The specific attributes reported by stakeholders include:

— **Population characteristics:** two stakeholders noted particular features of the Welsh population that make it conducive to undertaking research, including that immigration and emigration are low, leaving a stable population which can increase the efficiency of undertaking studies’ follow up. Another stakeholder referred to the small population which reportedly makes the country a natural test bed for undertaking research studies.

— **Research proximity to policy:** according to three stakeholders interviewed there are strong links between research and policy in Wales, meaning research can be translated into practice in shorter timeframes, thereby, allowing for more rapid benefits realisation. One of the stakeholders noted that in Wales they saw that research is used by the government to develop more evidence-based policies, increasing the visibility of the research they undertake and making the undertaking of research in the country more beneficial.

— **Links between primary and secondary care data:** three stakeholders from across the NHS and commercial research environment all reported that the main benefit of undertaking research in Wales is the quality of data available. Specifically, they noted that the linkages between primary care and secondary care data greatly benefit health research as well as economic and policy research. Other stakeholders added that data availability increases the efficiency of research
delivery and that the link between primary care and secondary care data results in a speedier feasibility process and more targeted patient recruitment.

While a number of stakeholders pointed to attributes of the Welsh economy and health and care landscape that make it attractive for conducting research, not all stakeholders were of this view. One stakeholder particularly reported that the nature of the Welsh research environment may deter sponsor companies. Specifically, it was highlighted that Wales’ relatively small population and country size means that research is limited to primarily small-budgeted studies, thereby, in their opinion, reducing the overall impact and value of research in Wales.

**Overall value of undertaking research in Wales**

Stakeholders reported that an active research environment has significant benefits in terms of research staff recruitment and retention, and more generally in terms of the quality of the research staff employed. This was said to be particularly important in Wales as stakeholders mentioned that recruitment of NHS staff can be more difficult compared to England.

Half of the stakeholders interviewed also referred to significant financial benefits to NHS organisations arising from undertaking research. For example, one stakeholder reported that significant savings are generated, both in terms of drug cost savings and salary savings and other NHS stakeholders referred to financial benefits in terms of grants received by commercial and non-commercial organisations to undertake research, and the investment in new equipment for some specific studies, which is then available for ongoing use after the trial is finished.

Additionally, stakeholders reported that they consider that an active research environment leads to:

— **Better clinical outcomes**: sites that take part in research tend to achieve better health outcomes for the whole patient population, not solely for the patients recruited in the study.

— **Better provision of care**: three different NHS stakeholders reported that involvement in research leads to better provision of care, and that undertaking research activity leads to better patients’ care at sites where the research is undertaken, even after the trial is over.

— **General improvement in standards and processes**: three NHS stakeholders interviewed reported that undertaking research usually leads to general improvements in standards and processes at the NHS organisations delivering the research, for example in terms of improved adherence to clinical pathways.

— **Access to treatment**: stakeholders highlighted the need to achieve equity of access to treatment in Wales. Half of the stakeholders interviewed as part of our study indicated that they believed that one of the most important benefits of undertaking research in Wales is that it gives access to treatment to people who would have otherwise not received it.

**4.2 Stakeholders’ views on the value added by the Support & Delivery Service**

Through the stakeholder interviews a number of key themes emerged linked to both the support provided in terms of study delivery, as well as broader areas of added value linked to wider activity, for example strengthening the research environment and providing greater opportunities for research in areas such as social care.

The key themes emerging from the stakeholder interviews are summarised below. It should be noted, however, that Health and Care Research Wales informed us that, based on the stakeholder comments, it considers that many of the views relate primarily to the S&D Centre’s role in the S&D Service, rather than the S&D Service itself. The S&D Service is made up of both the national S&D Centre and local NHS R&D departments.
Study delivery support

During our consultation, stakeholders identified that the S&D Service’s support in study delivery positively impacts on the efficiency, speed and costs with which NHS organisations are able to deliver studies. While stakeholders had a range of views around the specific aspects of support that added value to their organisations, there were some broad areas highlighted by stakeholders:

— **Study set-up:** according to five of the 15 stakeholders interviewed, the S&D Service adds value by supporting the set-up of studies in Wales, impacting primarily the timing and resourcing of studies. All the life sciences industry stakeholders we interviewed referred to this as of particular importance. Examples given of the study set up support that was of particular value included support for site selection, providing information on the capacity and capabilities of research sites and help to connect sponsor companies to principal investigators.

— **Staff capacity:** six of the 15 stakeholders interviewed referred to the S&D Service adding value to the Welsh research environment by funding research delivery staff at the NHS organisations. One stakeholder specifically said they thought that without the funding from the S&D Service while studies would still be funded by sponsor companies and charities, this commercial funding by itself would not be sufficient for the successful delivery of studies as there would still be the need for delivery staff.

— **Management of resources across Wales:** some of the NHS organisation stakeholders also pointed to the role of the S&D Service in coordinating research activity in Wales, by deciding how resources can be best deployed in a study, improving the efficient allocation of resources across Wales through prioritisation, which they felt enables a larger volume of research activity to be undertaken than would otherwise be the case.

— **One Wales Approach:** stakeholders also spoke about the impact of the S&D Service’s One-Wales approach, particularly focussing on the costings and contracts service, which is a standardised approach for reviewing and agreeing contracts and costings. According to one sponsor company, the single costing model makes Wales highly attractive for conducting health research, as the costing of studies is agreed transparently and fairly. Another sponsor company reported that the One-Wales approach is attractive as it speeds up the contracting processes and is more efficient as sponsor companies do not have to negotiate with each site independently. However, an NHS stakeholder reported that it considers that a One-Wales approach is not needed as in their experience sponsor companies want to undertake studies at established centres, and therefore the S&D Service’s efforts in spreading research across Wales may not work.

Wider Support & Delivery Service activity

A number of stakeholders pointed to the positive impacts that arise through the wider support and engagement activity undertaken by the S&D Service, for example, by offering training to researchers and delivery staff, stakeholders felt that the S&D Service adds value to the Welsh research environment.

Other areas of S&D Service activity that were considered by stakeholders to be beneficial include:

— **Offering networking opportunities and linking research institutions across the UK:** stakeholders referred to the value of events and activities supported by the S&D Service that help organisations to connect, collaborate with one another and facilitate a culture of sharing across networks. For example, different NHS stakeholders referred to the importance of annual events organised by the S&D Service in terms of: enabling networking and knowledge sharing; linking with researchers in different NHS organisations to establish joint patient recruitment processes; facilitating collaborations between NHS organisations and sponsor companies; and keeping NHS organisations up to date with the research activity outside of Wales.

However, three stakeholders from NHS organisations indicated that there would be benefit in the S&D Service increasing engagement with stakeholders when introducing new processes and
procedures, as well as involving wider stakeholders, such as universities, in the health and care research delivery.

— **Ring-fencing of funding:** stakeholders considered that ring-fenced funding for research activity helps to ensure that the resources are not used for other clinical activities and are not allocated to meet other demands. However, another NHS stakeholder reported that although the S&D Service’s funding is directed to the R&D teams at the NHS organisation for the delivery of studies, researchers still have to go through Health Boards to obtain approval for recruitment, which leads to significant delays and consequently unfilled research posts.

— **Supporting research approvals and research ethics processes:** approximately a third of the stakeholders interviewed indicated that the S&D Service adds value by supporting NHS organisations and researchers through ethics and permission processes. The standardisation of processes and approvals across Wales, specifically the research approvals and ethics processes, was said to lead to an increase in efficiency in study delivery both financially and in terms of time saved.

— **Excess Treatment Costs management:** two NHS stakeholders reported the management of excess treatment costs by the S&D Centre works very well.

**The additionality of the Support & Delivery Service**

As part of the interviews, stakeholders were specifically asked to provide views on the additionality of the S&D Service’s activity – that is how the S&D Service’s activity adds value relative to a hypothetical situation where the S&D Service was not provided and with no alternative in its place. Stakeholders provided a range of views on this:

— **Nature of health research:** according to a stakeholder, without the S&D Service the nature of the health research studies undertaken in Wales would be different, for example they felt that more observational, non-commercial studies would be undertaken, mainly led by university priorities rather than driven by clinical needs, and that commercial studies would become less complex. While one stakeholder felt that commercial research activity would not stop completely without the S&D Service, the nature of the studies would be different. A further stakeholder noted that without the S&D Service in place, and more specifically the R&D delivery team in each NHS organisation, they felt that studies would not be prioritised as effectively as they currently are, changing the nature of research undertaken.

— **Research delivery capacity and capability:** three out of the 15 stakeholders interviewed reported that they believe that without the S&D Service there would be a reduction in the research delivery capacity and capability in Wales, which would have a direct impact on patient recruitment to studies as well as the quality of staff dedicated to research. Stakeholders also commented that the governance of research would be put at risk, resulting in less co-ordinated research and lower quality standards.

— **Volume of research undertaken:** more than a third of the NHS stakeholders interviewed told us that they consider without the S&D Service in place significantly less research would be undertaken in Wales, with both non-commercial and commercial research activity being greatly affected. It was also noted by a further stakeholder that without the S&D Service they would be less able to target the right sites, and, therefore, Welsh research sites may not be considered for studies.

— **Diversification of sites:** if the S&D Service did not exist, two out of the three life sciences industry stakeholders interviewed reported that it would be more difficult, and require more resources, to scope the research sites, resulting in the same sites being selected for each study rather than new sites.

**56 The Support & Delivery Centre manages two centralised budgets to cover Excess Treatment Costs (ETCs) and Support Costs (SCs). Non-commercial studies that are eligible to apply for ETCs & SCs are added to the Health and Care Research Wales Portfolio. See: [https://www.healthandcareresearch.gov.wales/excess-treatment-costs-and-support-costs/](https://www.healthandcareresearch.gov.wales/excess-treatment-costs-and-support-costs/)**
sites across Wales being considered. Stakeholders noted that it is important to expand research capacity and avoid performance levels being driven down by over-utilisation of some sites. Another commercial stakeholder added that it is more difficult in Wales to find which investigators are interested in research in a certain therapeutic area, but the S&D Service helps greatly with this.
Appendix
<table>
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<tr>
<th>Glossary Term</th>
<th>Description</th>
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<tr>
<td>ABPI: Association of the British Pharmaceutical Industry</td>
<td>NHS organisations: In the context of this report, the seven Local Health Boards (Aneurin Bevan Health Board; Swansea Bay University Health Board; Cardiff &amp; Vale University Health Board; Hywel Dda Health Board; Cwm Taf Morgannwg Health Board; Betsi Cadwaladr University Health; and Powys Teaching Health Board.) and three NHS Trusts (Welsh Ambulance Services NHS Trust; Velindre NHS Trust Board; and Public Health Wales)</td>
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<tr>
<td>AIC: Additional Itemised Costs</td>
<td>NHS R&amp;D departments: NHS research and development departments based at each NHS organisation in Wales to help build local capacity and capability to support research</td>
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<td>CRO: Contract Research Organisation</td>
<td>NIHR: National Institute of Health Research</td>
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<td>CTUs: Clinical Trial Units</td>
<td>NIHR CRN: National Institute of Health Research Clinical Research Network</td>
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<td>DHSC: Department of Health and Social Care</td>
<td>ONS: Office for National Statistics</td>
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<td>FTE: Full Time Equivalent. This adjusts part time or temporary staff into an annual full-time equivalent based on the proportion of full-time hours worked over a year.</td>
<td>Portfolio: Health and Care Research Wales Portfolio. It is a comprehensive portfolio of the commercial and non-commercial research activity undertaken in Wales, which is supported by the S&amp;D Service.</td>
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<td>FY: Financial Year</td>
<td>PI: Principal Investigator</td>
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<td>GP: General Practice</td>
<td>R&amp;D: Research and Development</td>
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<td>GVA: Gross Value Added. GVA measures the contribution to the economy of an individual producer, industry or sector, net of intermediate consumption.</td>
<td>RDD: Welsh Government Research and Development Division.</td>
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<td>HRA: The Health Research Authority</td>
<td>Sponsor companies: An inclusive term for all companies funding commercial health and care research. This includes (but is not limited to) pharmaceutical companies, biotech companies and medical device companies.</td>
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<td>Industry-supported studies: all commercial and investigator-initiated studies funded by industry</td>
<td>S&amp;D Centre: Support &amp; Delivery Centre. It is responsible for facilitating the implementation of the Welsh Government’s policies and strategies</td>
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(i.e. a pharmaceutical company or medical device company) by providing centralised support functions across Health and Care Research Wales and on behalf of NHS R&D departments.

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<th>IIT: Investigator initiated trial. These are trials that are sponsored by NHS organisations or universities but where funding for the trial or trial drugs are provided by industry.</th>
<th>S&amp;D Service: Support &amp; Delivery Service. This is a Wales-wide service which provides a range of support functions to researchers and the public and aims to ensure that infrastructure is in place, at the national and local level, to deliver health and care research studies across Wales.</th>
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<tr>
<td>IRAS: Integrated Research Application System</td>
<td>UK: United Kingdom</td>
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<td>NHS: National Health Service</td>
<td>UKCRC: UK Clinical Research Collaboration</td>
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### Role of Health and Care Research Stakeholders in Wales

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<tr>
<th>Stakeholders</th>
<th>Description</th>
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| NHS organisations and other care providers | Health and care research on the Portfolio (see details of the Portfolio below) tends to be delivered through NHS organisations, and within wider health care settings, for example GP surgeries, community pharmacists and care homes.  
Delivery of non-commercial health and care research on the Portfolio is carried out by the Research Delivery Staff at NHS R&D departments, funded by the Welsh Government via the S&D Service.  
Commercial research is fully funded by commercial sponsors and generates supplementary income for NHS organisations and other care providers, which funds additional NHS staff to support the delivery of commercial health and care research. |
| Universities and academic CTUs     | Universities and academic CTUs receive grant funding to design and undertake non-commercial clinical studies. Studies that are part of the Portfolio tend to be delivered through NHS organisations and in wider health care settings, by health care professionals funded by the Welsh Government via the S&D Service. |
| Charities and other non-commercial funders | Charities involved in health and care research fund doctors and scientists in hospitals, universities and research institutes across the UK to undertake health and care research.  
For studies that are part of the Portfolio, the costs of delivering these studies is borne by the NHS R&D departments. |
| Life sciences sponsor companies and Contract Research Organisations | Pharmaceutical and medical device companies fund health and care research in Wales. These are commercial studies on the Portfolio, and although they can benefit from some NHS organisations’ support, the costs of the treatment as part of the trial are fully borne by the sponsor company through payments to the NHS organisations involved.  
In some instances, life sciences companies will employ Contract Research Organisations (CROs) to provide research services, from early stage biopharmaceutical development to preclinical research, clinical research and clinical trial management. |
## Table A2: Sources of data

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<tr>
<th>Analysis</th>
<th>Stakeholders</th>
<th>Summary of evidence gathered</th>
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<tr>
<td><strong>Economic impact in terms of GVA and employment</strong></td>
<td>S&amp;D Centre</td>
<td>— Data on the number of FTEs employed in the S&amp;D Centre and the associated staff costs, sourced from the S&amp;D Centre.</td>
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<td></td>
<td>NHS organisations</td>
<td>— Data on the number of FTEs employed in the NHS organisations’ R&amp;D departments and the associated staff costs, sourced from the S&amp;D Centre.</td>
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<td></td>
<td></td>
<td>— Data on the value of commercial per-patient payments received by NHS organisations from sponsor companies and CROs, sourced from NHS organisations.</td>
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<td></td>
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<td>— Data on the number of patients recruited onto commercial studies over the period in FY 2018/19, received from the S&amp;D Centre.</td>
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<tr>
<td><strong>Sponsor companies and CROs</strong></td>
<td></td>
<td>— Data on UK R&amp;D expenditure by the pharmaceutical sector, sourced from the ONS.</td>
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<td></td>
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<td>— The percentage of total UK R&amp;D pharmaceutical expenditure that is undertaken in Wales, sourced from the ONS.</td>
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<td>— The proportion of pharmaceutical R&amp;D that is spent on clinical research, sourced from ABP.</td>
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<td>— The return on investment of pharmaceutical R&amp;D, sourced from a study by Deloitte.</td>
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<td>— The proportion of studies on the Portfolio that are categorised as ‘device’ studies, sourced from the S&amp;D Centre.</td>
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<tr>
<td><strong>Charities and universities</strong></td>
<td></td>
<td>— Data on the breakdown of health research funding in the UK by types of health research activity and source of funding, sourced from the UKCRC. This provides us with the volume of total UK grant funding that relates to health and care research activity in Wales.</td>
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<td></td>
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<td>— The proportion of non-commercial health and care research activity put through the Portfolio, sourced from the ten NHS organisations.</td>
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<tr>
<td><strong>Payments to NHS organisations</strong></td>
<td>NHS organisations</td>
<td>— Data on per-patient payments made to NHS organisations for conducting commercial studies on the Portfolio, sourced from the NHS organisations.</td>
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<td></td>
<td></td>
<td>— Data on the number of patients recruited onto commercial studies on the Portfolio, sourced from the S&amp;D Centre.</td>
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<tr>
<td><strong>Cost savings to the NHS</strong></td>
<td>S&amp;D Centre</td>
<td>— Information on study protocols and the standard treatment from individual study protocols sourced from the Health and Care Research Wales database by the S&amp;D Centre.</td>
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<td></td>
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<td>— Data and information on drug dosages and prices for the standard treatments was sourced from (respectively) the emc database and NICE BNF database.</td>
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<td>— Data on the number of participants recruited onto commercial interventional drug studies included in the Portfolio (e.g. design type, recruitment numbers and dates), sourced from the S&amp;D Centre.</td>
</tr>
<tr>
<td><strong>Wider contributions</strong></td>
<td>Sponsor companies, CROs, principal investigator and researchers</td>
<td>We interviewed 15 stakeholders (3 life sciences industry stakeholders and 12 NHS stakeholders) to obtain more in-depth insights on:</td>
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<tr>
<td></td>
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<td>— the main ways the S&amp;D Service adds to the health and care research market in Wales;</td>
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<td></td>
<td>— what the clinical trial landscape would look like in the absence of the S&amp;D Service.</td>
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