Ipsos MORI
Social Research Institute

June 2019

Biomedical Catalyst Impact Evaluation

Final Report

Ipsos MORI and George Barrett

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Executive Summary

Ipsos MORI was commissioned in November 2014 to undertake an impact and process evaluation of the Biomedical Catalyst (in association with George Barrett). An interim study exploring both the effectiveness of processes employed to administer the programme and early signs of impact was published in January 2016. This second and final report from the evaluation focuses on the longer-term impact of the programme in stimulating R&D investment and accelerating the development of biomedical technologies led by industry and academia.

Biomedical Catalyst

The Biomedical Catalyst (BMC) was launched in 2012 as part of a wider package of measures to support the life sciences sector under the Government's Industrial Strategy. The programme made £240m of funding available to:

- Deliver growth to the UK life sciences sector;
- Deliver innovative life sciences products and services more quickly and more effectively into healthcare; and,
- Provide support to academically and commercially led R&D in a seamless, effective and efficient manner.

The Medical Research Council (MRC) and Innovate UK delivered the scheme in partnership, providing funding to translational research and industrial R&D projects at varying stages of technical and commercial development. The funds were allocated over eight competition rounds that took place between 2012 to 2015 and 257 projects were awarded funding. One hundred and eighty-four of these were funded by Innovate UK (awarded to 150 individual firms), 73 were awards made to PIs through the Development Pathway Funding Scheme (DPFS) by the MRC (awarded to 70 individual PIs). In addition, a further 56 Confidence-in-Concept (CiC) awards were made to 23 academic institutions[1].

Confidence in Concept

- The Medical Research Council committed £28m in funding to the Confidence in Concept programme over the period in the scope of this evaluation. This programme made awards to academic institutions to fund portfolios of smaller projects at the earliest stages of the translational pathway.
- The Confidence in Concept programme was viewed by institutions and PIs as addressing a gap in the availability of funding for very early stage proof-of-concept research. Most institutions sought to concentrate their funding on projects with potential for commercialisation, and involved industry and clinicians in structuring their priorities and award criteria to help them achieve this objective. There was evidence this has brought about changes in the way that projects are managed, with a greater emphasis on meeting key milestones and thinking through future steps along the translational pathway.
- The available data indicates that over 50 percent of Confidence in Concept awards made between 2012/13 and 2014/15 led to further funding from public or charitable research funders or the private sector, either to continue the development

[1] The MRC has also conducted a comprehensive and independent 10-year evaluation of MRC Translation Research 2008-2018 which includes outputs and impacts of the DPFS and CiC funding. The report can be downloaded at: https://mrc.ukri.org/publications/browse/10-year-translational-research-evaluation-report-2019/

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of the underlying translational concept or to explore other lines of inquiry arising from the project. Confidence in Concept also had a positive effect on the strength of the DPFS pipeline.

- The programme has led to notable economic outcomes. A total of 31 spin-outs emerged from the Confidence in Concept portfolio. These businesses – and particularly those active in advanced therapies – have been successful in raising private capital despite only recently being established. A total of £521m in venture capital funding was attracted by these companies by the end of 2018, supporting the creation of 141 jobs. The portfolio of spin-outs was valued at £843m. The programme also led to ten licensing agreements and two options to license, though there is no systematic data available on the value of these agreements.

- There were variations in the results of the programme across institutions. This was partly linked to the depth of the resources available to form links with industry and help applicants think through the next steps on the development pathway (some institutions were reportedly investing in translational research offices to address this latter issue). The data also highlighted the role of university linked investment funds in enabling the initial capitalisation of spin-outs, raising questions as to how far institutions without these capabilities could face constraints in achieving their commercialisation objectives.

Development Pathway Funding Scheme

- The Development Pathway Funding Scheme (DPFS) was originally established by the MRC in 2008 in response to the Cooksey Review. The scheme provides grant funding for translational research at preclinical and early clinical development stages. A total of £61m was committed to research projects over the period covered by this evaluation.

- DPFS funding had a positive impact of the ability of PIs and Co-Is to advance the translation of the technologies forming the focus of their applications. Those PIs whose applications were declined were frequently forced to abandon or postpone their research, suggesting there may be limited alternative options available to PIs to fund preclinical refinement and early clinical evaluation of products. DPFS funding allowed PIs to progress through the development pathway more rapidly than they would have done otherwise.

- However, DPFS projects were often long-term in nature, and at the time of this analysis, most were at advanced stages of completion but not yet complete. Many PIs had not fully processed the data gathered, had an opportunity to obtain follow-on funding, or publish the main findings from the project. As such, it is too early to provide a long-term assessment of the translational impacts of the DPFS projects funded under the BMC.

- DPFS has supported a wide variety of collaboration across disciplines, institutions and between academia, the NHS and industry. One of the most widely reported benefits of collaboration has been in terms of enabling PIs to acquire the project management skills required to efficiently manage the translational research process and partnerships with industry. Participation in DPFS projects was also reported to result in a legacy of greater commercial awareness that extended beyond the researchers directly involved in projects.

- Even though PIs commercialisation plans were generally in their infancy, the DPFS had a substantial economic impact through a portfolio of 13 spin-outs that were established by 2018. These spin-outs attracted over £500m in investment (£8.19 per £1 of DPFS funding committed) and were valued at over £1.3bn at the end of 2018. Comparisons between marginal applicants for DPFS funding suggests that a high share of these outcomes would not have happened in the absence of the programme.

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- Even under conservative assumptions, the evidence suggests that the economic value of the programme has substantially exceeded its costs. Allowing for uncertainties in attributability to MRC funding, the results imply a potential range for the benefit-to-cost ratio of £1.72 to £16.39 per £1 funding committed.

Innovate UK grants

- The BMC also involved the commitment of £125m in grant funding for industrial research and development. This included awards for early stage proof of concept studies (Feasibility Studies), and funding for early preclinical and later stage clinical development (Early and Late Stage Awards).

- Businesses funded through the programme progressed more rapidly through the translational pathway than those that did not receive funding. It is estimated that firms moved their assets forward 1.3 TRL stages further through the development pathway than they would have done without funding,

- The awards made through the BMC to industry led projects had an enduring effect on R&D spending. It is estimated that the programme led to an increase in overall R&D spending of £248m to £350m by 2018. Allowing for public contributions of £141m, it is estimated the programme levered an additional £0.76 to £1.48 of private R&D spending per £1 of public sector spending. This was accompanied by an increase in the number of R&D workers employed by these businesses. The grants awarded increased employment by 11 to 15 percent over 3 to 5 years (net of deadweight), equivalent to the creation of 234 to 330 jobs. While the programme was efficient in leveraging private R&D spending, its effects were at the margin of overall private spending on R&D in the sector (which totalled £4.3bn in 2017).

- The results also showed that the BMC had a significant effect on the ability of businesses to leverage additional venture finance from the private sector. It is estimated that the 150 firms benefitting from the programme raised between £563m and £710m in private investment as a direct result of the programme. Allowing for all Innovate UK grants received by these businesses, the estimated leverage ratio was between £3.99 and £5.09 per £1 of public spending.

- Few applicants had launched products to market at the point of the evaluation. The evaluation found no impact on the turnover or productivity of those businesses that received support through the programme.

Conclusions

- Impact against objectives: Overall, the BMC has proven to be a successful programme in stimulating investment in the life science sectors and accelerating the development of healthcare technologies. It has largely delivered against its two core objectives relating to impact – including delivering growth to the UK life science sector and to deliver innovative life sciences products and services more quickly and more effectively into healthcare.

- Leverage: The results of the evaluation also suggest that the programme was an efficient instrument for achieving its objectives. All components of the programme leveraged substantial additional resources into translational research and industrial R&D. Each £1 of funding made available to the CiC programme was matched by £1.46 of funding from private or charitable sources. The Innovate UK grants led to an additional £0.76 to £1.48 in private R&D spending per £1 of public sector spending by 2018. Comparisons with evaluations of other initiatives suggest the programme has been, at minimum, as effective as R&D tax credits in stimulating private R&D investment. The findings broadly align with past research examining the impact of public and charitably funded medical research on private R&D spending.

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- Value for money: A cost-benefit analysis of the grants awarded to businesses by Innovate UK related the benefits of the programme embodied in the increase in the value of businesses supported suggested that the BMC also offered strong value for money, with a central estimate of the benefit to cost ratio (BCR) of £4.72 per £1 invested. This substantially exceeds the hurdle rate of return typically applied in the approval of the Business Cases for these types of scheme. It is more challenging to determine the rate of return on MRC's investments in translational research, though the evidence suggests that the economic value of commercialisation outcomes achieved by 2018 substantially exceeded the costs incurred in funding the CiC and DPFS programmes (a range of £1.72 to £16.39 per £1 committed for the DPFS).

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1 Introduction

Ipsos MORI was commissioned in November 2014 to undertake an impact and process evaluation of the Biomedical Catalyst (in association with George Barrett). An interim study exploring both the effectiveness of processes employed to administer the programme and early signs of impact was published in January 2016. This second and final report from the evaluation focuses on the longer-term impact of the programme in stimulating R&D investment and accelerating the development and commercialisation of innovation health and life science technologies.

1.1 Evaluation aims and objectives

While Phase One of the evaluation of the Biomedical Catalyst (BMC) gave attention to process and impact evaluation issues, this second phase focused on assessing its longer term impacts. As specified in the Invitation to Tender, the evaluation sought to provide a comprehensive view of the impacts of the BMC versus the counterfactual (i.e. what would have happened in the absence of the programme). The impact areas of interest are highlighted in the table below.

Table 1.1: Evaluation Questions

Impact Area	Questions
Funding for healthcare innovation	▪ The impact of the BMC on the funding 'landscape' for R&D in the sector ▪ Leveraging investment finance for the development of the projects
Technical Progress	▪ Whether projects fit the high-quality, high-risk profile intended ▪ The extent to which research into innovative healthcare advances have been supported ▪ How quickly (how many) products have moved through the development pathway ▪ The extent to which participation in the BMC has contributed to improved direct and indirect participant performance
Skills and Collaboration	▪ The extent to which participation in the BMC has enabled new collaborative partnerships or activities (SME or academic) and the added value of these partnerships ▪ Acquisition or access to new skills or expertise, or resources;
Economic impact	▪ Increased employment, profitability or productivity
Spill-overs	▪ Extent to which the BMC has led to other impacts beyond the organisations directly involved. ▪ Whether particular themes in the innovative science are being de-risked
Social benefits	▪ Improved health outcomes

Source: Innovate UK and MRC monitoring information

As highlighted in the report, there are some areas in which it has not been feasible to provide definitive results as it is too early to provide an empirically grounded assessment. These relate to the impact of the programme in de-risking areas of innovative science (demonstrating the safety and efficacy of novel treatments and crowding-in investment) and the extent of knowledge spill-overs. These effects can - in principle - be explored using rigorous quantitative methods, but require consideration over a more extensive time horizon.

The exploitation of novel healthcare innovations can involve extensive timelines, particularly in drug discovery. As such, it was not possible to provide a systematic assessment of the health benefits associated with the programme as few products

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had reached wide scale adoption at the time of writing. However, these future benefits will – to some degree - be implicit in other measures (e.g. increases in the valuations of businesses). Finally, the evaluation did not involve a bibliometric analysis to examine the scientific impacts of the programme. This was covered in detail as part of a wider MRC review of its translational research funding since 2008[2].

1.2 Methodology

This report is based on a range of evidence gathered by the team over the course of the evaluation:

- Literature review: A rapid literature review was completed to investigate the changes in the funding landscape for translational and healthcare research in the UK since the programme was launched.

- Analysis of management information (MI) and secondary datasets: The evaluation team undertook further analysis of the management information available from Innovate UK and the Medical Research Council. This included reviewing the application-level data from the Medical Research Council and Innovate UK and publicly available data on the performance of the life sciences sector to examine the strength of the rationale for the programme.

- Survey: In Phase One of the evaluation, a census telephone survey was undertaken with all applicants submitting a full-stage application to the BMC in the first six competition rounds who did not opt out. In Phase Two, these applicants were re-interviewed to find out explore further progress made. Applicants to rounds seven and eight were also approached to boost the sample size and representativeness of results.

  The survey was based on a sample of 337 applicants to the programme. This comprised 182 applicants in rounds one to six that were contacted in the first wave of the evaluation and had agreed to be re-contacted, and 154 additional applicants to rounds seven and eight. There were 195 respondents to the survey (a response rate of 57 percent), comprising 78 applicants that were awarded funding (a response rate of 66 percent) and 117 applicants whose applications were declined (a response rate of 54 percent). Response rates amongst academics and businesses were 57 percent.

  While response rates to the survey were comparatively high, coverage of the overall population was reduced by the need to run an opt out process amongst industrial applicants as part of the first phase of the study. This reduced the sample of applicants for Feasibility Studies that could be contacted. In terms of coverage of the population, the survey covered:

  - Applicants for DPFS funding: Forty-five percent of PIs awarded funding through the DPFS, and 31 percent of those whose applications were declined (a total of 72 applicants).

  - Applicants for Innovate UK funding: Evidence was gathered from 60 percent of those applying for Late Stage Awards, 32 percent of those applying for Early Stage Awards and 18 percent of those applying for Feasibility Studies. This equated to a total of 123 applicants (39 Late Stage Awards, 28 Early Stage Awards and 56 Feasibility Studies).

  These sample sizes were sufficiently large to support analysis at the level of the overall portfolio, but did not support detailed comparisons between subgroups of applicants. Coverage rates were affected by reduced sample availability driven by the need for an opt-in process as part of the first phase of the study, the share of those contacted as part of

[2] See MRC Translational Research, 2008 to 2018, Medical Research Council, September 2019.

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the first phase of the study agreeing to be re-contacted (which reduced available samples by around 20 percent), and sample attrition (for example, arising from the closure of businesses or difficulties in obtaining up to date contact details). There is a risk of non-response bias in those findings on impact that were driven by survey findings, particularly in relation to Feasibility Studies. To the degree that non-response was driven by closure of businesses, which was more common amongst unsuccessful applicants, this may lead to an understatement of the effects of programme. Applicants to the Confidence in Concept (CiC) programme were not included in either of the surveys as the delegated nature of the funds lent themselves more to qualitative forms of exploration.

- Data-linking: To compensate for reduced sample availability, records of those applying for grants were linked to administrative and other datasets to provide comprehensive evidence of the outcomes of interest. This enabled the inclusion of all applicants for funding in the analysis, giving more robust findings than would have been feasible from the survey alone. This included extracting details from Companies House filings for all businesses and PIs to determine whether the business was still trading, validate observations on R&D spending, employment and turnover gathered through the survey, determine whether PIs had founded a spin-out, and where they had, collect information on investment in, and the growth of, the business. Records of businesses associated with the programme were linked to the Business Structure Database within the ONS Secure Research Service to give longitudinal data on the employment and turnover of individual businesses, and to Pitchbook[3] to provide annual data on equity investments, IPOs, M&A deals, and the valuations of businesses where available.

- Case Studies: In Phase One of the evaluation, a total of 20 case studies were undertaken covering five Confidence in Concept awards, five unsuccessful applications and ten projects which were the subject of successful applications. All 20 project teams were approached through follow up research but only 15 of the original 20 were able to feed into the evaluation. While the evaluation team approached 10 replacement case studies, only two more project teams responded to requests to be involved. The case studies involved triangulation of documentary evidence (application forms, appraisal data, and monitoring data) with qualitative research with applicants and collaborators and wider secondary evidence. Each case study covered issues relating to the strength of the scientific, commercial, and health rationale for the project, funding issues, progress made, the wider effects of the project, and broader commercial exploitation plans. The table below provides an overview of the profile of the 12 grant funded projects examined in the case studies (i.e. excluding CiC awards).

  For Confidence in Concept awards, case studies involved initial discussions with the Research Office and interviews with a sample of PIs leading individual projects. These discussions also examined the effects of BMC funding on broader aspects of institutional behaviour around translational research and industry-academic collaboration.

[3] Pitchbook captures and structures disclosures (e.g. through press releases) in relation to venture capital, private equity, and other investments.

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Table 1.2: Case Study Profile

Characteristic	Number of Cases
Type of applicant	DPFS (6), Feasibility Study (2), Early Stage (2), Late Stage (2)
Status of award	Successful (8), Unsuccessful (4)
Modality	Small molecules (4), Antibodies (1), Diagnostic (2), Vaccine (1), Medical Device (2), Assay (1), Tool (1)

Source: Innovate UK and MRC monitoring information

1.3 Structure of this Report

The remainder of this report is structured as follows:

- Section 2 – Biomedical Catalyst: This describes the rationale for the programme and intervention logic, and a brief overview of changes in the funding landscape since the programme was launched.
- Section 3 – Confidence in Concept: This section provides an overview of the impacts of the Confidence in Concept awards funded by the MRC between 2012 and 2016.
- Section 4 – DPFS: The section examines the impacts of the Development Pathway Funding Scheme.
- Section 5 – Innovate UK awards: This section examines the impact of the Feasibility Studies, Early and Late Stage awards made to industrial applicants.
- Section 6 – Conclusions: The report concludes with an overview of the programme's impacts against its objectives and highlights issues that could be considered in the development of future schemes.

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2 Biomedical Catalyst

This section provides an overview of the BMC programme, covering its aims and objectives, anticipated outcomes, and an overview of the portfolio of projects that were funded (drawing on an evaluation framework prepared as part of the baseline evaluation study completed in 2015). This section also provides a brief outline of changes in the wider context for the programme since it was launched.

2.1 Biomedical Catalyst

The BMC was launched in 2012, building on the Development Pathway Funding Scheme (DPFS) established by the Medical Research Council (MRC) in 2008 in response to the Cooksey Review by extending the scope of funding available to projects led by industry. The scheme was launched as part of a wider package of measures to support the life sciences sector under the Government's Industrial Strategy. The programme made £240m of funding available to:

- Deliver growth to the UK life sciences sector;
- Deliver innovative life sciences products and services more quickly and more effectively into healthcare; and,
- Provide support to academically and commercially led R&D in a seamless, effective and efficient manner.

The MRC and Innovate UK delivered the programme in partnership. The programme offered funding for translational research and industrial R&D projects at varying stages of technical and commercial development. This funding largely took the form of grants made to Principal Investigators (PIs) and businesses to deliver proof of concept, pre-clinical, and clinical studies with the aim of accelerating the commercialisation or translation of novel therapeutics, diagnostics, medical devices, and digital health products. Awards were also made to academic institutions to fund portfolios of smaller projects at the earliest stages of the translational pathway through the Confidence in Concept programme.

2.2 Logic Model

The life science sector is of strategic importance to the UK. It is a highly productive, R&D intensive, component of the UK economy, and has its foundations in a world class academic research base. The expansion of the programme was partly motivated by major strategic issues faced by the UK life science industry in the early 2010s. At the time, the sector faced challenges including an extended period of declining R&D productivity and expected loss of revenues from the expiry of patents on 'blockbuster' products. This led to disinvestments in R&D by large pharmaceutical businesses. This was partly offset by a growth in biotechnology start-ups and the emergence of new industries (e.g. digital health). However, the global financial crisis of 2008 led to a widespread withdrawal of the risk finance upon which these businesses depended to fund their activities, placing constraints on their growth.

The programme aimed to tackle these issues by:

- Stimulating investment in R&D and translational research: In the short to medium term, grants awarded through the programme were expected to lead to increased levels of R&D spending and/or translational research. This assumed that the funds would not be used to deliver activities that the private sector would have funded anyway or encourage the diversion of resources from parallel programmes of development activity either within the organisations receiving grants

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or across the sector overall. This could be accompanied by an increase in the employment of R&D workers or a greater focus of on translation amongst PIs (as opposed to efforts to develop greater understanding of disease biology).

- Supporting technological progress: In turn, additional investment in R&D or translational research will support further refinement activity at proof of concept, preclinical and clinical stages of development. While the translational pathway is often depicted as a linear process, these studies may lead to revision of hypotheses or the discovery of gaps in fundamental understanding of disease biology, stimulating further avenues of inquiry.

- Attraction of further funding: The progress achieved during the delivery of the project will de-risk investment in the project from the perspective of an external investor. In the case of academic led projects, this may increase the likelihood that the team secures further public or charitable funding. There may also be an increase in the probability that the technology is transferred to the private sector via a licensing agreement or through the establishment of an external commercial vehicle (a spin-out). Provision of grant funding will also help de-risk the balance sheet of the business as it increases the cash available to the business without diluting its equity. As applications for funding are subject to a rigorous due diligence process, there may be further benefits in terms of quality signalling to potential investors. Additional finance raised will support further refinement of the underlying technology.

- Knowledge spill-overs and demonstration effects: The programme may also result in wider benefits in terms of generating knowledge (such as improved understanding of disease biology) that could be built on or exploited by others. These effects could be mediated by the publication of findings from preclinical studies or clinical trials, through formal or informal interactions between researchers, or via circulation of researchers in the labour market. The programme has also supported the development of novel technologies (e.g. cell and gene therapies) characterised by high levels of risk. To the degree that the research funded has helped demonstrate that these technologies are safe and effective, this may de-risk investment in analogous technologies, stimulating the commitment of additional resources to R&D and product development. These effects will occur over long time frames, and are not considered in detail in this evaluation.

- Long-term benefits: In the long-term, the programme may produce benefits that arise from the exploitation of the technologies being developed. These benefits could include improved quality of life for patients or cost savings for national health systems. While this evaluation was undertaken some six years after the launch of the programme, these types of effect will take substantially longer to arise and have not been considered in detail as part of this study. It should also be noted that given the scale of resources needed to take many products through Phase III clinical trials (and to manufacture, market and distribute products post market authorisation), eventual exploitation may be led by a third party (such as a large pharmaceutical business) under license or through their acquisition of the technology developer.

An overall logic model for the programme, summarising the causal processes involved, is set out in the figure below. The figure highlights those outcomes that would only be observed in the academic and industrial sectors, and assumes that eventual exploitation of the intellectual property developed would be taken forward by the private sector.

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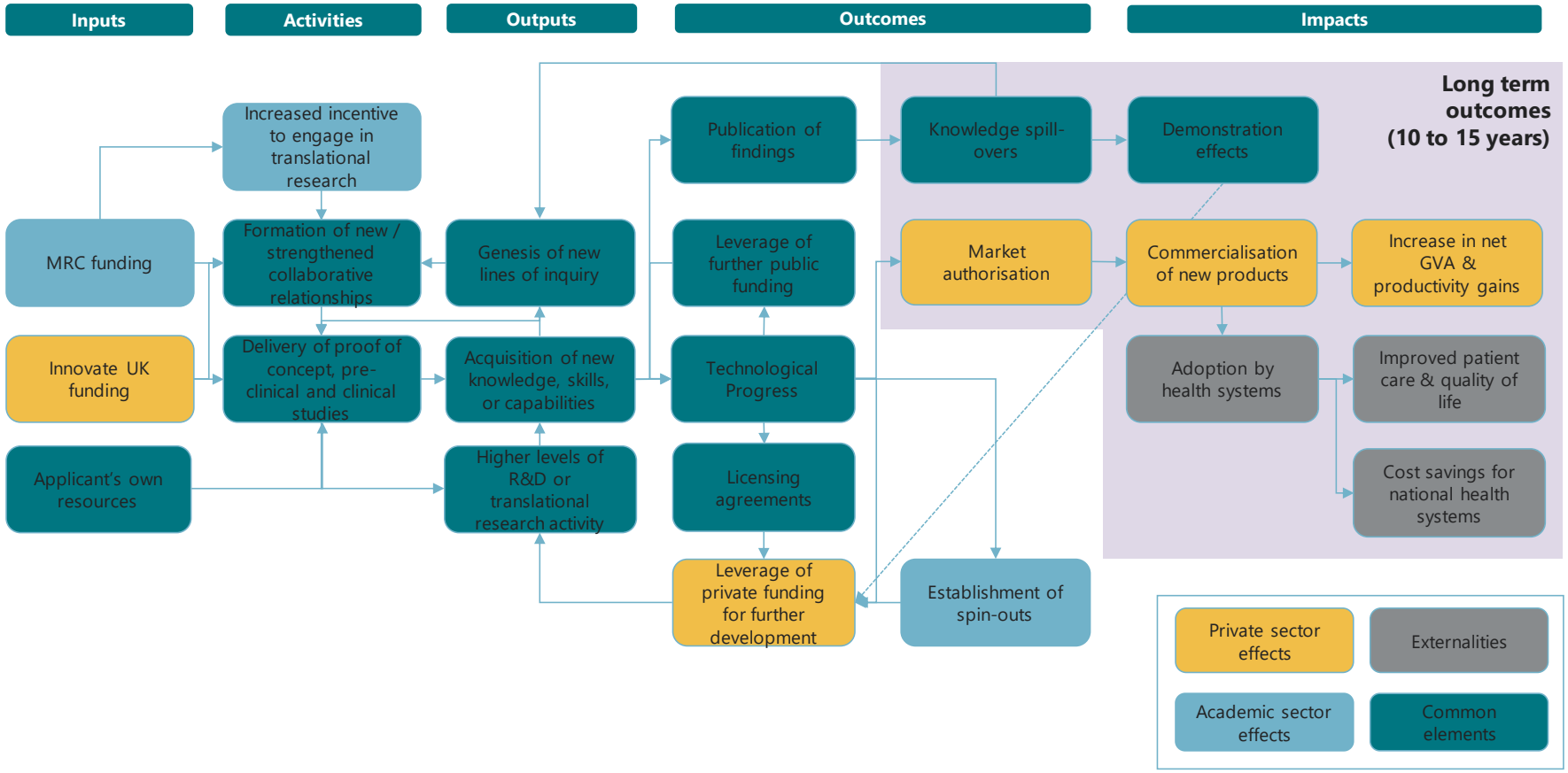
Figure 2.1: Logic Model



2.3 Wider context

2.3.1 Sector Context

The global pharmaceutical market, valued at $1.1 trillion in 2015, is expected to continue growing at 5.5 percent per annum, driven largely by growth in the sales of small molecules and biologics[4]. The UK is a major centre for pharmaceuticals and medical technology with more than 4,000 companies in core industries[5] producing a combined output of some €19bn in 2015[6]. All of the major players have a presence in the UK and two of the 'top ten' have their headquarters here. The sector employed some 64,000 people in core 'biopharma' and a further 97,000 in the medical technology industries in 2017[7]. The traditional strength of the sector is reflected in a GVA per employee of more than £150,000 and R&D spend which accounts for some 20 percent of the national total[8].

The UK has evident strengths and potentials in key areas, including in relation to future treatments such as cell and gene therapy and complex medicines such as new vaccine treatments, as well as in the production of established medicines. The sector is also dynamic – it is estimated that 657 of the active businesses in the sector (16 percent) were incorporated since the programme was launched in 2012[9]. While many these businesses were active in more traditional industries – 133 were engaged in the development or production of small molecule pharmaceuticals and 255 in medical devices – there was also substantial growth in the numbers of businesses active in more novel industries. For example, 49 developers of advanced therapies were established since the programme was launched (more than half of those captured in the OLS Bioscience and Healthcare Technology Database), alongside 171 that were active in the digital health sector (35 percent of the industry).

However, despite the impressive headline numbers, major pharmaceuticals based here and in other western countries face substantial challenges. Competition from generics and associated pressures on profitability have contributed to trends towards the offshoring of both clinical trials and manufacturing activity to lower cost locations in Asia and South America. Within the UK there have been underlying trends towards falling employment and productivity, and a recent paper by Jones and Wilsdon published by Nesta[10] also points to diminishing returns to its R&D investment, with rates of return which fall below the costs of capital. As illustrated in the figure below, real terms R&D spending has fallen from its peak of £5.4bn in 2011 to £4.3bn in 2017. The authors also argue that the 'model' which has been adopted in which R&D has been extensively externalised to 'hard' IP based spinouts funded by venture capital investment which expect to generate returns through trade sales to larger players has not been successful.

There is also a widespread recognition that the UK's manufacturing sector does not entirely match the strengths of its research base, with long term problems in securing the full successful commercial exploitation of its academic research and in growing substantial new UK based pharmaceutical companies. These problems tend to be at least partly ascribed to the weaknesses of its VC community compared with that of the USA, with SMEs often unable to secure a supply of 'patient' capital accepting of the inevitable major risks associated with drug development.

[4] Outlook for Global Medicines through 2021, Quintiles IMS.

[5] Strength and Opportunity 2017, Office for Life Sciences, excluding service and supply industries.

[6] The Pharmaceutical Industry in Figures, Key Data 2018, EFPIA

[7] Strength and Opportunity 2017, Office for Life Sciences, excluding service and supply industries.

[8] Business Expenditure on Research and Development, ONS, 2017

[9] Based on the data tables underpinning Strength and Opportunity 2017, Office for Life Sciences, excluding service and supply industries.

[10] Jones R and Wilsdon J (2018) The Biomedical Bubble Why UK research and innovation needs a greater diversity of priorities, politics, places and people

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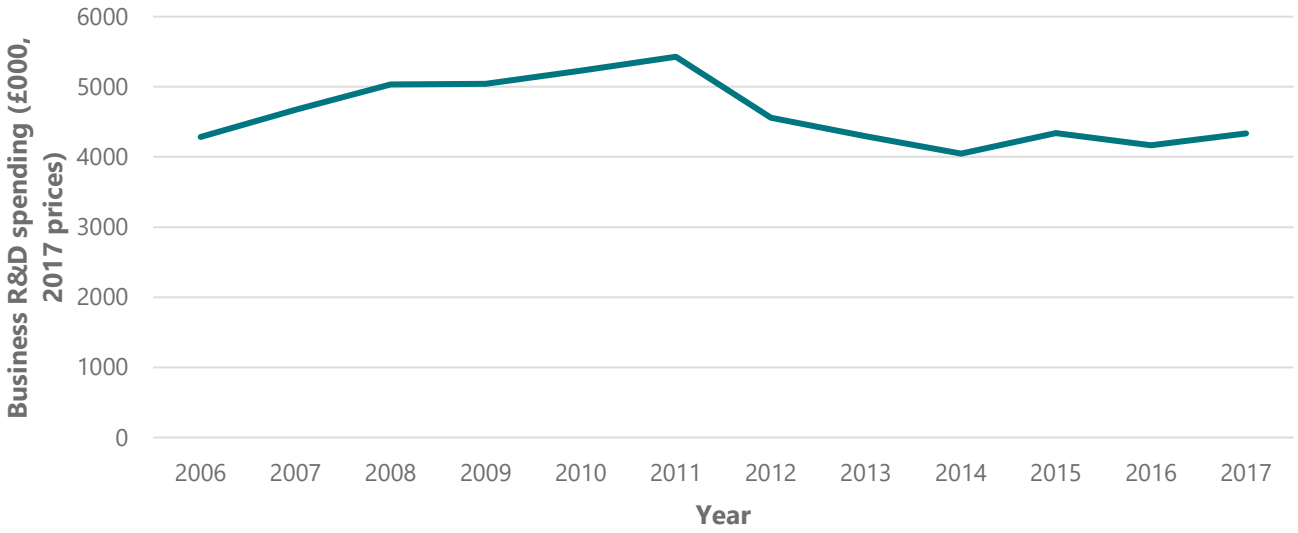
Figure 2.2: Business R&D spending in pharmaceuticals, 2006 to 2017, £000s (2017 prices)



Source: Business expenditure on Research and Development 2017, Office for National Statistics, November 2018.

2.3.2 Public support for life sciences

The UK life science industry benefits from substantial investment in fundamental biological science and translational research in academic institutions, as well as a direct and indirect support for industrial research and development. The main public sector funders of research are the MRC, the National Institute for Health Research (NIHR) and Innovate UK. Public investment in specific translational research schemes have their origins in the 2006 Review of UK Health Research Funding[11] (Cooksey Report). The report noted that the UK research system had a long tradition of undertaking "excellent basic science" but concluded that "the UK is at risk of failing to reap the full economic, health and social benefits that the UK's public investment in health research should generate". The Office for Strategic Coordination of Health Research (OSCHR) was established to oversee the budgetary and research strategies of the MRC and the NIHR and improve the coherence and comprehensiveness of funding arrangements for supporting translation of ideas from conception. Specifically, the MRC were to provide project funding for the early part of the translational pathway, and the NIHR to cover the later stages (late clinical trials and Health Technology Assessments).

This led to the establishment of several strategic programmes in 2008. This included the MRC led Development Pathway Funding Scheme which provided funding for preclinical and early clinical trial activity and the MRC and NIHR led Efficiency and Mechanism Evaluation programme (late clinical evaluation through to Phase III or equivalent) to progress translational research projects through the development pathway. This was extended to funding for industrial R&D with the publication of the 2011 Strategy for UK Life Sciences[12] and the launch of the BMC. The BMC itself was extended in 2016. Several other schemes to support translational research and industrial R&D were delivered in parallel:

[11] Sir David Cooksey (2006) A Review of UK Health Research Funding, Sir David Cooksey. Available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/228984/0118404881.pdf (accessed June 2019).

[12] Department for Business, Innovation and Skills and Office for Life Sciences (2011) Strategy for UK Life Sciences. Available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/32457/11-1429-strategy-for-uk-life-sciences.pdf (accessed June 2019).

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- MRC grant funding schemes: The MRC established numerous other schemes to support translational research in parallel to the DPFS. These tend to have tended to focus on translational research at the earliest stage (i.e. providing a pipeline of projects that could potentially be funded through the DPFS), on specific challenge areas (e.g. Regenerative Medicines), or enabling technologies that support wider translational efforts (e.g. the Methodology Research Programme).

- Innovate UK grant funding: Innovate UK has funded industrial R&D within the life science sectors on a more general basis through CR&D and Feasibility Study competitions. The openness of the competition scopes has increased with time. Prior to 2016, CR&D competitions tended to be focused on addressing a specific challenge defined in the competition scope (e.g. Stratified Medicines Innovation Platform), though as the agency moved a sector based approach in 2016 and to a wholly open approach in 2018, the level of core funding specifically targeted at the life sciences sector has fallen.

- Catapults: Innovate UK also supports commercialisation of research discoveries through its Catapults - the Cell and Gene Therapy and Medicines Discovery Catapults, and the Cell and Gene Therapy Manufacturing Centre - which provide infrastructure and teams of experts to translate early stage research into commercially viable and investable therapies (£26 million from Innovate UK in 2017/18). These centres are focused on drug discovery and manufacturing, and there is no equivalent for medical technology.

- NIHR: The NIHR also provides funding to support translational research via the Invention for Innovation (i4i) scheme which funds collaborative R&D projects within medical technology SMEs, academic institutions and the NHS, with the aim of de-risking projects that have demonstrated proof-of-principle and have a clear pathway towards adoption and commercialisation that would make them attractive to follow-on funders and investors. The expected i4i output is an advanced or clinically validated prototype medical device, technology or intervention. The i4i Connect scheme provides an additional funding stream aimed at SMEs who require a 'funding boost' to reach the next stage in the development pathway and to be able to apply for further funding. While there are parallels with the BMC, these schemes are smaller scale (receiving £12.8 million in funding in 2017-2018) and does not encompass drug discovery activity.

- Charitable funding: The charitable sector is a strong contributor to UK health R&D funding. The Association of Medical Research Charities (AMRC), whose membership includes 140 charities in the UK, estimate a total investment of £1.6 billion in research from charities during 2017. Ninety-two percent of this research takes place in academic institutions and hospitals in the UK. The £1.6bn invested by the charitable sector represents a considerable proportion of research expenditure in the UK, compared to circa £1bn annual research expenditure of the NIHR (NIHR 2017) and £0.8bn of the MRC. Several UK charities, including the Wellcome Trust, Cancer Research UK (CRUK), the British Heart Foundation (BHF), and Arthritis Research UK (ARUK) have funding streams relating directly to translational research or covering some aspect of the translational pathway within their calls for proposals. It should be noted that this funding tends to focus on proof-of-concept studies and does not generally provide scale of funding needed for preclinical and early clinical evaluation activities supported by the DPFS.

Life sciences also figure prominently in the Government's Industrial Strategy[13] which builds upon the development of the technology and innovation roadmap and the report by Sir John Bell's "Life Science Industrial Strategy"[14] which set out a

[13] HM Government (2017) Industrial Strategy: Building a Britain Fit for the Future. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/664563/industrial-strategy-white-paper-web-ready-version.pdf (accessed June 2019).

[14] Sir John Bell (2017) Life Sciences: Industrial Strategy. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/650447/LifeSciencesIndustrialStrategy_acc2.pdf (accessed June 2019).

variety of recommendations with the aim to drive growth, increase productivity, improve the use of data, reinforce the science base, deepen skills and deliver benefits to patients. The report's recommendations have been taken forward in the establishment of the Medicines Manufacturing Challenge as part of the Industrial Strategy Challenge Fund which aims to support the development and manufacturing of advanced therapies, medicines and vaccines as well as the development of digital health technologies. The programme encompasses seven strands of activity funded through a combination of a public spending commitment of some £175m and a range of private sector match funding.

Going forward, the UK's Departure from the European Union raises important, still to be resolved, issues around the UK's future relationship with the European Medicines Agency - and what this will mean for regulatory and approval processes – as well as for the future relationship with the European Single Market. It is clearly premature to draw conclusions about how this will affect the attractiveness of the UK as a location for R&D and/or manufacturing activity at this stage. However, in the absence of counter measures, there could be a potential adverse impact on the availability of venture capital (VC) to the sector from the loss of the European Investment Fund as a cornerstone investor in UK based funds[15].

2.3.3 Private investment

The available data (as shown in Figure 2.2) suggests that whilst the UK benefits from much the largest share of capital raised by the life science sector of any European country, the amounts involved fall short of those raised within some of the major clusters in the United States. However, the UK pharmaceutical, biotechnology and medical technology sectors have clearly benefitted from a recovery in the supply of finance which has taken place following the 2008 financial crisis. Inevitable year to year fluctuations and limitations in the coverage of the available data series make it difficult to judge how far this trend is being sustained, whilst apparent shifts in the pattern of investment may be substantially influenced by the impacts of small numbers of IPOs rather than representing fundamental market shifts. The volume of funding has also grown more rapidly than the number of deals, indicating a shift towards larger deals, perhaps reflecting the importance of transaction costs to the sorts of deals sought by VC funds.

Data on UK pharmaceutical and medical technology investments between 2012 and 2018 suggest that they tend to be smaller than average in comparison to those heaquartered in leading European and US clusters (an average of £6.7m relative to £25.6m in New Jersey, £18.9m in Germany, and £16.6m in Massachussets). However, there is evidence that the average deal sizes rose between 2015 and 2018, driven by a number of large scale public fundraisings. The data also suggests that the availability of seed investment in the UK has grown substantially in recent years[16], reflecting the tax incentives associated with Venture Capital Trusts and the Enterprise Investment Scheme and the life sciences sector has been a substantial beneficiary of this improvement. However, as the findings of HM Treasury Patient Capital Review show, investment vehicles are often risk averse and seek relatively short term exits which clearly influences their likely willingness to fund drug development projects.

[15] HM Treasury (2017) Financing Growth In Innovative Firms: Consultation Response. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/661398/Patient_Capital_Review_Consultation_response_web.pdf

[16] British Business Bank (2018) Small Business Finance Markets Report 2018. Available at: https://www.british-business-bank.co.uk/wp-content/uploads/2018/02/Small-Business-Finance-Markets-2018-Report-web.pdf (accessed June 2018).

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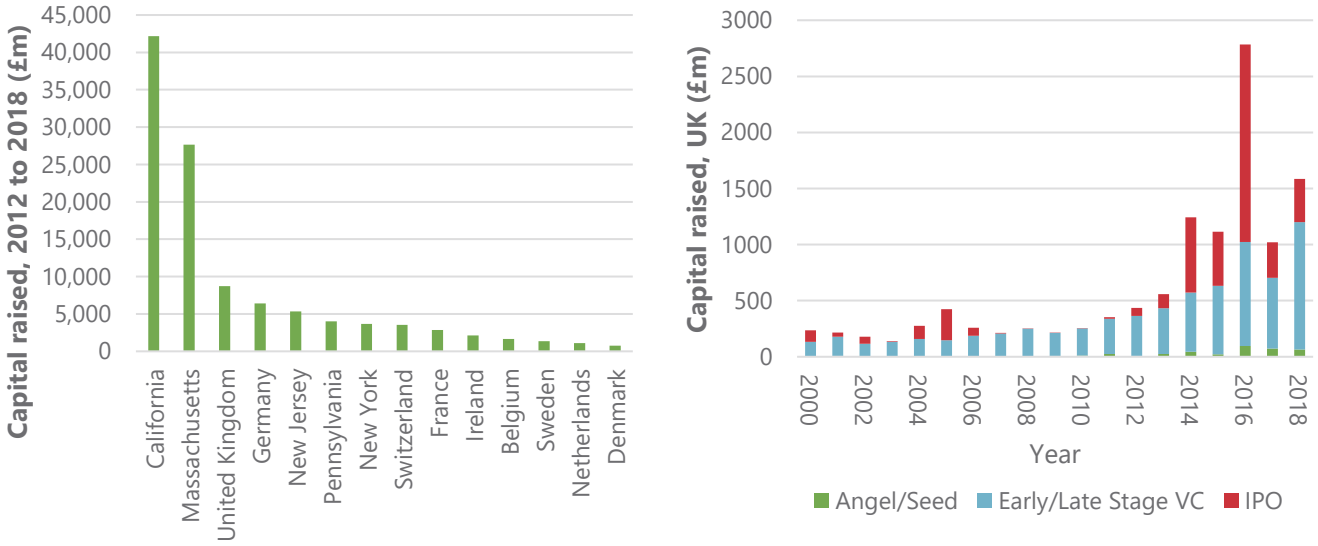
Figure 2.3: Venture Capital and IPOs, Pharmaceutical and Medical Technology Sectors, 2000 to 2018



Source: Pitchbook, Pharmaceutical and Healthcare Devices and Supplies, Completed Deals by HQ location, top 5 US states and major European countries.

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3 Confidence in Concept

Key Findings:

- The Confidence in Concept programme was viewed by institutions and PIs as addressing a gap in the availability of funding for very early stage proof-of-concept research. Most institutions sought to concentrate their funding on projects with potential for commercialisation, and have involved industry and clinicians in structuring their priorities and award criteria to help them achieve this objective. There was evidence this has brought about changes in the way that projects are managed, with a greater emphasis on meeting key milestones and thinking through future steps along the translational pathway.
- The available data indicates that over 50 percent of Confidence in Concept awards made between 2012/13 and 2014/15 led to further funding from public or charitable research funders or the private sector, either to continue the development of the underlying translational concept or to explore other lines of inquiry arising from the project. PIs indicated that the data acquired through the project had a substantial effect on their ability to develop competitive applications for preclinical research funding.
- Confidence in Concept had a positive effect on the strength of the DPFS pipeline. Applications originating in Confidence in Concept awards were scored more highly by the DPFS panel and were more likely to be awarded funding. However, this also entailed greater competition for resources, and the programme may have led to an increase in the share of potentially fundable proposals that were declined.
- The programme has led to notable economic outcomes. A total of 31 spin-outs emerged from the CiC portfolio. These businesses – and particularly those active in advanced therapies – have been successful in raising private capital despite only recently being established. A total of £521m in venture capital funding was attracted by these companies by the end of 2018, supporting the creation of 141 jobs. The portfolio of spin-outs was valued at £843m. Even excluding one outlying success with a particularly high valuation, the economic value embodied in these spin-outs substantially exceeded the £28m in funding committed to the programme over the period. The programme also led to ten licensing agreements and two options to license, though there is no systematic data available on the value of these agreements.
- There were also signals that the programme produced wider outcomes within academic institutions, particularly in terms of raising the profile of translational research and providing opportunities for Early Career Researchers to develop their careers.
- There were variations in the results of the programme across institutions. This was partly linked to the depth of the resources available to form links with industry and help applicants think through the next steps on the development pathway (some institutions were reportedly investing in translational research offices to address this latter issue). The data also highlighted the role of university linked investment funds in enabling the initial capitalisation of spin-outs, raising questions as to how far institutions without these capabilities could face constraints in achieving their commercialisation objectives.

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A key component of the BMC is the Confidence in Concept (CiC) programme led by the MRC. This scheme provides devolved funding of up to £1m to academic institutions to be spent over a 24-month period, via an annual application process. The primary objective of the scheme is to support translational research programmes at the earliest stages of development, allowing researchers to compile proof of concept data in support of applications for more substantive funding (e.g. via the DPFS). The funding can also be used to support the formation or strengthening of collaborative relationships between industry and academia, though funding is not available for IP protection or the costs incurred by industrial partners from their involvement in research projects.

This section provides an assessment of the effectiveness of the CiC programme, based on a review of monitoring information captured through annual application forms and Researchfish (though Researchfish is known not to provide a complete record of the outputs and outcomes of academic research projects), five detailed case studies involving in-depth interviews with the co-ordinators of CiC funding and a sample of PIs receiving CiC awards, and an analysis of relevant secondary data where available. The MRC has also conducted a comprehensive and independent 10-year evaluation of MRC Translation Research 2008-2018 which includes outputs and impacts of the DPFS and CiC funding[17].

3.1 Confidence in Concept awards

Over the period covered by this evaluation (2012/13 to 2014/15), 56 CiC awards were made to 23 academic institutions. These institutions were awarded £28.1m in MRC grant funding in total[18]. While responsibility for allocating funds was delegated to institutions, details of individual projects funded are provided in annual applications for funding. Based on application forms submitted in 2017[19], 516 research projects were supported of which 480 were reportedly complete, 22 were on-going, and ten were terminated early[20]. Projects tended to be comparatively small scale, receiving an average award of £59,000[21].

Institutions were given flexibility to develop their own strategic priorities and fund other types of activity to support translational research within their institutions. The five case studies were used to explore the degree to which, and how, institutions chose to use this flexibility:

- Strategic priorities: The five institutions all adopted a comparatively open strategy for allocating CiC funding, with limited ring-fencing of resources for projects targeting a specific disease area and/or modality. There was some evidence of priorities evolving as time passed (e.g. aligning the programme more closely with the needs of the NHS or increasing the focus on small-molecules).

- Use of funding: Four of the five institutions reported they had used their funding to grant fund research projects. One elected instead to fund a core team of chemists and biologists to work with PIs on research projects.

- Supplementary activities: One of the five institutions funded supplementary (i.e. non-research) activities - residential workshops for researchers to interact with industry representatives and members of the CiC award panel established by the institution to obtain feedback in improving their applications.

[17] The report can be downloaded at: https://mrc.ukri.org/publications/browse/10-year-translational-research-evaluation-report-2019/

[18] Based on CIC application forms records from May 2018, covering the first three rounds of CiC.

[19] Based on MRC's extraction of information from CIC application forms, which are reported to MRC on a self-assessed basis.

[20] The status of four projects was unknown,

[21] This figure is based on the value of individual awards reported by institutions.

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- Complementary funding: In addition, CiC application forms suggest that institutions drew on a wide range of other sources of funding to deliver their programmes. For awards for which data was available[22], this included £17.2m of their own funds, £7.9m from industry sources, and £12.4m from other sources[23]. This brings total funding for the programme to at least £63.2m over the period and implies each £1 of CiC funding was matched with £1.46 of funds from other sources (note that this does not include follow-on funding for further development of the ideas being explored by PIs).

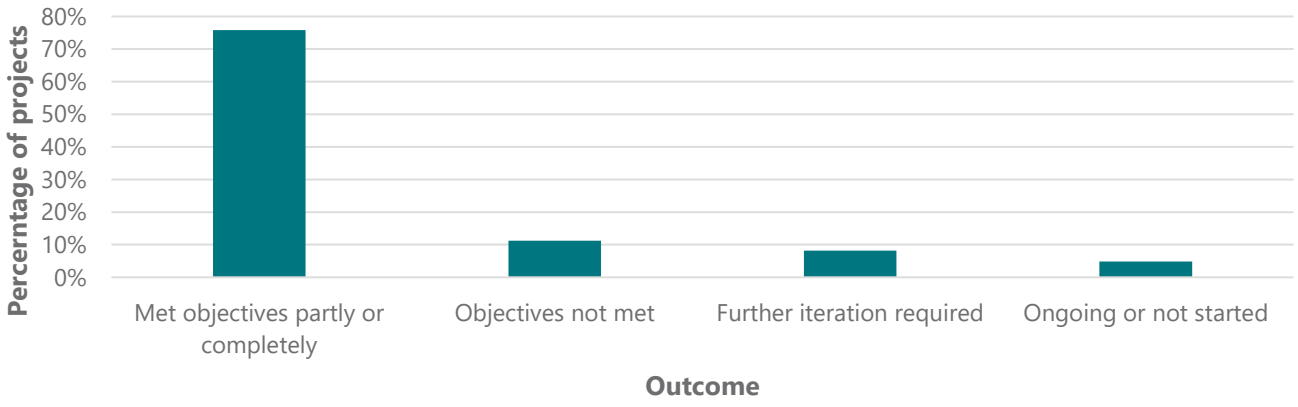
All five institutions reported that they prioritised projects that presented a clear commercial route to translation (over non-commercial routes). This was achieved by involving industrial partners on award panels or by working with industry to understand how CiC funding could help de-risk projects to the point at which they might attract private investment. Respondents also emphasised the importance of clarity of thinking regarding the next steps on translational pathway and considerations around intellectual property in making awards (one reported that the main reason for rejection at the CiC panel was weaknesses in the commercial case for funding the project).

This emphasis on commercialisation and scope to attract follow-on funding was thought to have influenced the types of projects that were funded. An observation was made that the annual application process may encourage panels to prioritise funding projects that can attract the next tranche of funding more rapidly. For example, while device or a diagnostic can reportedly move quite quickly into the next development stage, a longer route is usually required for a small molecule (which may need additional CiC grants to get the data package enabling an application for DPFS).

3.2 Project results and outputs

Academic institutions are asked to provide a self-assessed view on the success of the project in terms of how far it showed confidence in the underlying translational concept. Around 76 percent of projects were reported to have met their objectives (party or completely), eight percent required further iteration, and a further 15 percent did not meet their objectives or were terminated early (as illustrated in Figure 3.1). The case studies did not incorporate a review of a sufficiently large number of projects to validate this success rate. However, a similar pattern was observed across the 10 projects examined through the case studies. In six cases, the researchers involved reported that the study provided confirmatory proof of concept data, while the hypotheses relating to the original translational concept were not supported in four cases.

Figure 3.1: Self-assessed outcome of Confidence in Concept Awards, 2012 to 2015



Source: MRC extraction of 2017 CiC application forms

[22] Covering £25.6m of the £28.1m awarded.

[23] Other sources of funding includes charitable funding or funds from other Research Councils (e.g. Impact Accelerator Accounts).

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In terms of some key self-reported outputs from the projects funded:

- Publications: A total of 193 projects (37 percent) were reported to have led to a publication. A total of 528 publications were attributed to these projects. It is not clear from the self-reported data why a higher share of projects did not result in a publication given the proportion of project that reportedly met their objectives. It is likely that in some cases, publication of findings will be deferred to protect the intellectual property built up in the project.

- Patents: Seventy-five projects (13 percent) were reported to have led to new patent applications. It should be noted that these patents may not always have significant intrinsic value. For example, one project reviewed as part of the case studies resulted in two patent filings, though the findings of the underpinning study did not find that the family of proteins being explored as targets in cancer were as fundamental as originally hypothesised.

- Spin-outs: Thirty-one projects (5 percent) were reported to have led to a spin-out.

- Medical products: One medical product (a diagnostic to monitor neutrophil elastase) was reported to have emerged from the project portfolio, reaching marketing authorisation in 2017. The product was being commercialised by one of the spin-outs established on the back of data produced with CiC funding.

3.3 Additionality of CiC funding

One of the aims of CiC was to address a perceived funding gap between fundamental science and translational research where researchers found it difficult to obtain the proof-of-concept data needed to make a successful application for funding for more substantial programmes of research. It is difficult to provide a statistical test how of how far CiC met this goal, owing to challenges in observing the overall volume of early stage translational research completed within academic institutions. However, the case study research was used to gather views on the impact of the programme on levels of early stage translational research activity:

- Absence of alternative funding options: Four of the five institutions engaged explicitly reported that the CiC had a positive influence over the volume of early-stage research projects taking place within their institution. The primary reason offered was that there were limited alternative sources of funding that could be deployed for the same purpose. While other internal sources of funding were available, these were not specifically aimed at translational research and are substantially more competitive, and the projects were generally not sufficiently advanced to access funding from the institution's TTO or form the focus of a larger grant application. Some also commented that the only other source of funding available for early stage translational research projects were EPSRC's Impact Accelerator Accounts, for which many projects (e.g. those in drug discovery or diagnostics) would not be eligible. As such, the general view was put forward that many PIs would refocus on fundamental science in the absence of this funding.

- Risk appetite: One institution indicated it took a less risk-averse approach with the CiC fund than with other funds, and used the expertise of panel members and the translational research office to identify projects which, although risky, had potential to be de-risked and would subsequently have potential for high rewards. The institution highlighted that it often had the option to fund a small component of a larger project led by well-established PIs, and while this may have generated impressive outputs, CiC funding would not have made a material difference to the result.

- Alignment of funding: Another institution reported that the CiC played a critical role in aligning other sources of funding towards a common aim, where it was used to fund translational research in conjunction with three Biomedical Research Centres (BRCs). The institution expressed concern that a loss of CiC funding would likely result in these research centres

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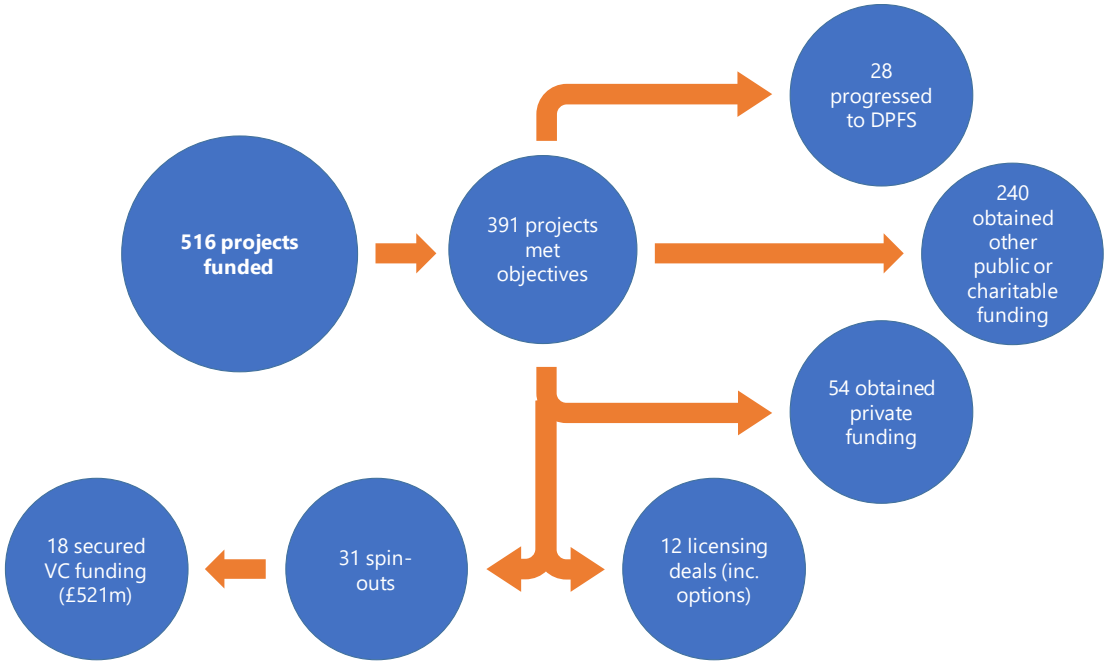
withdrawing their funding from the central pot. This would mean that projects not aligning to specific BRC objectives would go unfunded, estimated by the respondent at about 10 percent of projects.

3.4 Further funding

Researchers will generally need to attract further funding from the MRC, other research funders, or the private sector (via a spin-out, a licensing agreement, or some form of collaboration agreement) to progress through the translational pathway. Overall, 51 percent of projects (267) were reported to have attracted further funding, and the diagram below illustrates the distribution of these outcomes across these possibilities (which are not mutually exclusive – a single project could attract funding from multiple sources).

Figure 3.2: Further funding attracted by CiC projects



Source: CiC application forms, Companies House, Pitchbook. Note that funding outcomes are not mutually exclusive.

3.4.2 Progression to DPFS

Records of projects funded through CiC between 2012 and 2015 were linked to full applications to the DPFS between 2012 and 2018[24] to help assess the degree to which the core translational concept had advanced and understand the impact of CiC on the DPFS pipeline. This showed:

- Short term imprint on DPFS portfolio: A total of 37 (of 211) full applications to the DPFS between 2012 and 2015 could be linked to research programmes that had previously been supported with CiC funding.
- Quality: The data showed that applications originating in CiC scored more highly than those that had not benefitted from this funding. The average score awarded to applications originating in CiC between 2012 and 2015 was 7.0 relative

[24] Note that Ipsos MORI did not have data on outline applications made to DPFS, and links could not be made to declined DPFS applications beyond 2015 owing to limited data available in relation to content of these applications.

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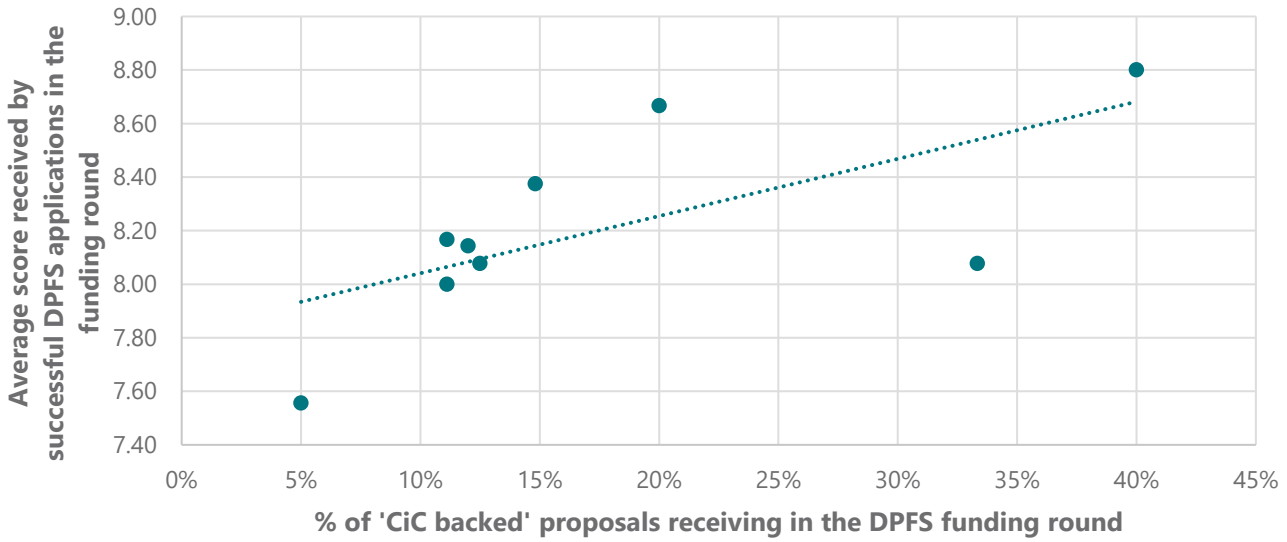
to 6.4 for other applications. Applications originating in CiC awards were also more likely to be awarded funding (45 percent compared to 30 percent of other proposals)[25].

- Longer term effects: A further eleven projects originating in CiC were funded through the DPFS between September 2015 and September 2018. Overall, 28 CiC projects progressed to DPFS funding (seven percent of the 391 projects that met their objectives) accounting for 20 percent of all DPFS awards made over the period (141).

As such, the CiC programme appears to have had an effect in raising the strength of the pipeline of projects for consideration by the DPFS panel. This may have led to greater competition for funding and pressure on available resources. Those DPFS rounds involving higher shares of CiC backed projects were associated with higher average scores for applications awarded funding and (to a lesser extent) higher shares of potentially fundable applications being declined[26]. This interpretation was supported by one PI making a successful application for follow-on DPFS funding, who remarked that while they may have made the application without the data generated by the CiC project, it would not have been as competitive.

Figure 3.3: Correlation between the share of 'CiC backed' applications received in each DPFS funding round between 2012 and 2015 and the average scores received by successful applications



Source: MRC monitoring data

There was substantial variation in progression rates across institutions. Six institutions saw more than ten percent of their CiC projects progress to DPFS, while four institutions did not see any. These patterns did not appear to be linked to simple resource allocation patterns such as overall funding levels or the average size of the awards made. The case studies covered two institutions that saw lower rates of progression to DPFS which pointed to some factors that have been important:

- One respondent gave the view that lower progression rates to the 'disease agnostic' approach (i.e. beginning with an understanding of a compound and its mechanism of action without taking an initial view on which disease in which it may offer a therapeutic benefit) taken by the institution to many of its project, creating challenges in articulating the

[25] These differences were significant at the 90 percent level of confidence but not at the 95 percent level of confidence.

[26] A project has been considered to be potentially fundable if it scored '7' or higher at the DPFS panel.

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underlying medical rationale and placing those projects at a disadvantage relative to those involving a conventional pathway given the DPFS award criteria.

- A second remarked that that it would be unusual for a single CiC project to produce a sufficiently large package of data to support an application to the DPFS. The monitoring data showed that only a small share of PIs received successive CiC awards to develop an underlying translational concept (of 487 PIs receiving funding, 29 received multiple CiC grants), and the case studies indicated that some PIs turned to other funding sources to complete the data package required. For example, one used CiC funding to demonstrate the feasibility of completing a clinical trial of a psychological intervention and sought charitable funding to demonstrate that the intervention could be administered, before progressing to the trial itself. One respondent suggested that these patterns could be linked to perceptions within institutions that they could only report 'once' on a particular project in their annual funding applications.

- A final point made was that projects often gave opportunities for Early Career Researchers, but time gaps in funding following the completion of CiC projects created problems in retaining staff, resulting in loss of momentum and the abandonment (or shelving) of projects.

3.4.3 Other sources of public and charitable funding

Data provided through the CiC application process indicated that a high share of projects obtained follow-on funding from other research funders (around 46 percent of the 516 projects funded between 2012 and 2015). However, this data is self-assessed, and it is not always clear how far the funding relates to the core translational concept or another avenue of inquiry that emerged from the project. The case study research suggested that of the ten projects reviewed, three obtained follow-on funding for the core translational concept (either from DPFS or from charitable sources). However, a further two projects led to further funding for related projects (e.g. to develop an alternative vaccine based on the technology platform developed through CiC).

In discussions with institutions and PIs, it was suggested that the primary benefit of CiC in securing follow-on funding was its role in providing the data needed to provide more convincing evidence in support of applications for larger tranches of funding. For example, one respondent reported that previous research highlighted some obvious targets for a protein based therapeutic, and the CiC grant helped fund experiments that the pilot data had indicated would be worth carrying out. The funding helped generate some key data which was used in a successful Wellcome Trust investigator application.

"We probably would have struggled through without it but it might have taken longer, and time is everything, particularly if one's trying to push it forward and translate it and end up with a product."

When speaking to one university, the scheme was considered to enable it to demonstrate that it has a pipeline of opportunities, raising the profile of its translational research culture and helping to generate funds from other sources:

"Being able to demonstrate that we have a process, that we can manage distribution of funding through the scheme, manage projects and move them forward, has enabled us to leverage hopefully some additional money coming from another source to plug a gap for pilot data. It's an essential part of the whole translational scheme."

However, the case studies suggested that in some cases, project lifetimes are being extended due to the 'unpreparedness' of institutions to progress funded projects to the stage where novel concepts and technologies can be exploited. For

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example, one institution reported that they did not have the resources to support all funded projects to work out what their next steps should be in terms of taking the technology forward and how to achieve this. This has meant that projects can take longer than necessary to develop. In recognition of this, the institution is setting up a translational research office: a team of three people to look after this pipeline of projects, among others, and advise researchers on what milestones they should set during the project and what routes they should use to take the project forward.

3.4.4 Industrial collaboration

The evidence gathered showed that industrial routes to progression were at least as common as applications for follow-on funding to the DPFS. Monitoring information reported by institutions suggests that 54 projects (around ten percent of the projects funded) secured some form of private funding. Again, there was substantial variation across institutions – while six institutions levered private funding into at least 15 percent of their CiC portfolio, there were seven institutions that did not lever private funding into any of their CiC projects. The case studies yielded some possible explanations for this variation:

- Industry involvement: A comment was made that CiC projects were typically at too early a stage to generate significant interest from industry (and this is supported by the apparently low rates of industrial collaboration in the delivery of CiC projects). However, those institutions that were more successful in levering follow-on funding from the private sector tended to secure greater levels of engagement from industry in the award panel or in other advisory capacities. These institutions tended to seek industrial input in helping and structure the CiC programmes locally to ensure it was focused on industrial needs.

- Project management: One institution reporting higher levels of industrial engagement reported that it initially funded CiC projects as 'normal' academic research projects with substantial scope for exploration and without clear milestones, which did not lead to significant progression outcomes (and the institution lost its CiC grant). The institution introduced a more rigorous approach to managing funded projects in response (suggesting that the threat of losing funding can be an effective tool in changing behaviour), ensuring that they have clear deliverables and milestones and that these can be monitored and evaluated. Projects were also selected on the strength of the potential pathway for development, with applicants required to be clear about how the projects will be managed, what they will deliver and the follow-on steps.

- Resources: Some explanations for variable levels of industrial engagement were couched in terms of the level of resource they could commit to supporting PIs in forming the required relationships. Proximity to Discovery funding (a parallel MRC programme) was deemed to be helpful in addressing these issues. One institution without Proximity to Discovery funding reporting difficulties in attracting industry partners to support the delivery of the CiC funded research and attributed this to the institution's inability to provide matched funding and the lack of resource to support applicants (and reported they were intending to apply for this funding to address the issue).

3.4.5 Licensing

There is limited information available on the licensing outcomes associated with the programme. Based on the information provided in application forms, ten projects led to a licensing agreement (in three cases to spin-outs that emerged from the wider CiC and DPFS portfolio) and a further two projects led onto an option to license the technology. Additionally, the data also suggested that in a further three cases, licensing discussions were at advanced stages. No systematic data was recorded in terms of licensing revenues (or the headline values of the agreements) that could be used to estimate the overall economic value embodied in those agreements (largely due to commercially sensitive nature of this information).

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3.4.6 Spin-outs

Monitoring data suggests that the CIC portfolio between 2012 and 2015 was productive in terms of stimulating spin-out activity. Thirty-one spin-outs were attributed to CiC grants (including both those reported through Researchfish and additional disclosures through the annual application process[27]). Most spin-outs were established between 2015 and 2017. Of those included in the OLS Bioscience and Healthcare Technology database (18 of 31 companies), 11 were engaged in the development of novel therapeutics with the remainder focused on medical technologies (novel devices or digital health) or providing CRO/CMO services.

The spin-outs were mostly recently established companies. However, data extracted from their most recent accounts filing and wider information available through Pitchbook suggested that 18 had secured either some form of equity investment or convertible loans to progress their activities. The total level of investment attracted by these companies (based on figures on Pitchbook) totalled £521m (though this total is skewed by £373m raised by a single company through an Initial Public Offering in 2018). Only four of the 31 companies had been dissolved (or remained dormant) since establishing, while two were established too recently to report account filings at the time of the research.

The data highlighted a range of underlying variation in these results:

- Advanced therapies: The most successful companies appear to have been those that were active in advanced therapies (cell or gene therapies). The five companies active in this segment raised £447m in comparison to £74m raised by other businesses operating in other subsectors.
- University VC funds: The data also highlighted the importance of universities own investment funds in capitalising spin-outs. Around six of the 18 spin-outs obtaining VC backing received seed funding from investment funds with links to the originating institution (e.g. Cambridge Enterprise Fund, UCL Business, Oxford Sciences Innovation, or IP group). This raises questions as to how far institutions without access to this supporting infrastructure will face challenges in commercialising technologies emerging from the CiC portfolio.
- Business expansion: Two companies (both developers of advanced therapies) have diversified their pipeline substantially through acquisition activity. In one case, the company acquired a portfolio of ex-vivo gene therapies from a large pharmaceutical firm for an upfront fee of £10m. In the second case, the company acquired a Portuguese biotechnology business developing immunotherapies, acquiring eight additional assets.
- Economic impact: The spin-outs had collectively created a total of 141 jobs. The total pre-money valuation[28] of the spin-outs established totalled £843m at the time of their most recent investment. Again, this was skewed by one outlying firm with a high valuation (£749m), and the remainder of the portfolio was valued at £94.2m. It has not been possible to establish the degree to which these outcomes can be directly attributed to the CiC programme. However, the economic value embodied in these businesses substantially exceeds the £28.1m investment made by the MRC.

[27] Note that this excludes around 10 claimed spin-outs that were either established overseas and those that were incorporate before the CIC programme began. Additionally, there is some overlap with the portfolio of spin-outs emerging from the DPFS portfolio.

[28] This measure excludes the additional value in the business resulting from cash assets associated with the investment, giving a clearer measure of investor's expectations regarding the potential profits associated with the underlying pipeline.

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3.5 Wider impacts

The case studies also highlighted numerous other types of impact associated with the CiC programme.

Changing translational research culture

Several respondents suggested that CiC helped to alter perceptions of the value of translational research within academia. For example, one institution reported that CiC funding helped to raise the profile of translation as a worthwhile activity, and reward and recognise people working in this area, encouraging more researchers to spend time on translational research. The availability of a dedicated MRC funding source for early translational projects was seen as significant in terms of backing up this awareness-raising with money to support work in this area. One institution commented that CiC funding had helped draw attention to the early stages of the pipeline, and the focus of the scheme on looking ahead to the next step was thought to have been valuable in exposing post-doctoral researchers to this way of thinking.

It is important, however, to note that CiC was not the only driver of reported changes in culture. For example, one institution also suggested that wider developments in the local innovation system, including the establishment of local venture capital funds that have capitalised spin-outs emerging from CiC projects, and the launch of a Biomedical Research Centre, have all raised the profile of translational research within institutions concerned. Additionally, some respondents noted that changes in culture are not universal, reporting that more could be done to engage senior leadership at the institution in terms of making the case for investment in early translational research.

Project management

As noted above, one of the effects of the CiC was to encourage a re-evaluation of management approaches and the adoption of more rigorous approaches to project management:

"Previously we had let them get away with stock phrases like 'We will apply for DPFS funding' - which is what we want them to do, but we were maybe a bit guilty there of not having enough clarity, as we need to separate the really strong applications from those that are still good, but the applicants may not have really thought out the follow-on steps."

One institution explained that a key benefit of the CiC proof of concept funding is that it enabled it to show in an academic environment the importance of commercial thinking and portfolio management. Articulating its portfolio in both academic and clinical terms helps to demonstrates expertise and strengths to attract more industry and other funding. They also highlighted that CiC funding has encouraged academics to engage more along a translational path:

"I can't underestimate the influence this type of funding has, not just as a source of funding, but as a way of helping the translation culture evolve within the university."

Collaboration

Respondents also highlighted several ways in which CiC had been beneficial in supporting different types of collaboration:

- Interdisciplinary working: One institution highlighted that in each round, between one-half and two-thirds of applicants were unknown to the Panel, providing an opportunity to identify potential inter-departmental or inter-faculty connections between groups that may not have otherwise been aware of each other.

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- Collaboration with industry: One institution highlighted that by funding a team with particular technical skills usually only found in industry, the CiC grant changed the way in which industry interacts with the unit, as on collaborative projects it is able to do more of the work in-house. This means that industrial partners have been prepared to work with the unit for longer than they would otherwise.

"One of the projects we ran recently with [pharmaceutical business] – usually someone goes to their site and is tutored by them to run through their screen. Because they know we are highly competent they send assay-ready plates up to us and it's run in-house. What the CiC allows us to do is have enough protein to run the 250,000 compounds they were giving us. We went through four rounds of expansion with them – they are prepared to work with us longer because they know if they get to the back end of this we have the technical competence, and some funding, to take it on."

- Collaboration with clinicians: One institution used the funding to support collaboration with clinicians at the nearby teaching hospital, by including a clinician from the hospital on their scientific advisory board. This engagement added value to the unit's thinking by providing a clinician and patient viewpoint on the feasibility of using certain treatments. In some cases, this had led to projects being abandoned after clinicians advised that the resulting drugs would not be acceptable to patients.

"What working with this unit makes everyone realise is that even having a clinician who thinks the technology is great is not enough. It's got to sit with their priorities in terms of: what are they really interested in procuring? It pushes you another step further."

Skills

The case studies also highlighted numerous ways in which the CiC helped to deepen the skills available to the institution:

- Attracting staff: The availability of a dedicated funding source for early translational projects was seen as significant in terms of helping to attract people to the institution by demonstrating both its support for translational research, and the availability of small scale proof of concept funding.

- Leadership and supervision skills: The PI for one CiC-funded project commented that the funding had given them valuable experience in running a team and improving their leadership and supervisory skills. This experience, combined with the recognition gained from being awarded CiC funding, was described as "pivotal" to their career and contributed to securing major grants since. The PI also commented that the experience had made them more focused on the importance of being very clear about what a project is trying to achieve and how to move to the next stage with it.

- Development opportunities for ECRs: One institution indicated previous research records and CVs are less of a factor in awarding funding compared to major funding streams, and the scheme tends to see more early career researchers as the PI, who are then able to show that they have won a grant.

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4 Development Pathway Funding Scheme

Key Findings:

- DPFS funding had a **substantial impact of the ability of PIs and Co-Is to advance the translation of the technologies forming the focus of their applications.** Those PIs whose applications were declined were frequently forced to abandon or postpone their research, suggesting there may be limited alternative options available to PIs to fund preclinical refinement and early clinical evaluation of products.
- DPFS funding **allowed PIs to progress through the development pathway more rapidly than they would have done otherwise.** However, DPFS projects are often long-term in nature and at the time of this analysis, most were at advanced stages of completion but not yet complete. Many PIs had not fully processed the data gathered, had an opportunity to obtain follow-on funding, or publish the main findings from the project. Although a high share of PIs intended to continue development of the underlying translational concept, it is too early to provide a long-term assessment of the translation impact of the DPFS projects funded under the BMC as insufficient time had elapsed since the projects had concluded (if indeed they had concluded at all).
- **DPFS has supported a wide variety of collaboration across disciplines, institutions and between academia, the NHS and industry.** One of the most widely reported benefits of collaboration has been in enabling PIs to acquire the project management skills required to efficiently manage the translational research process and partnerships with industry. Participation in DPFS projects was also reported to result in a legacy of greater commercial awareness that extended beyond the researchers directly involved in projects.
- PIs encountered some hazards that were possibly foreseeable at the outset of the project. This does not appear to have had a material impact on their ability to achieve the objectives of the MRC grants. However, the long-run translational impact of the DPFS will be dependent on the ability of the PI to continue their work beyond the lifetime of the grant, and projects plans are not always robust to the hazards that might arise (e.g. supply chain stability). It is advised that as well as encouraging PIs to think through the steps in the translational pathway beyond the lifetime of the grant as part of the application process, they should also be asked to consider longer-term risks that could block their future progress.
- Even though PIs commercialisation plans were generally in their infancy, **the DPFS has had a substantial economic impact through a portfolio of 13 spin-outs that were established by 2018.** These spin-outs have **attracted over £500m in investment (£8.19 per £1 of DPFS funding committed) and were valued at over £1.3bn at the end of 2018.** Comparisons between marginal applicants for DPFS funding suggests that a high share of these outcomes would not have happened in the absence of the programme.
- Even under conservative assumptions, the evidence suggests that the economic value of the programme has substantially exceeded its costs. Allowing for uncertainties in attributability to MRC funding, the results imply a **potential range for the benefit-to-cost ratio of £1.72 to £16.39** per £1 funding committed.

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This section examines the impact of projects funded through the Development Pathway Funding Scheme (DPFS) between 2012 and 2015 as part of the BMC. This section draws on primary survey research completed with DPFS applicants in 2018, case studies of a sample of funded and unfunded projects, and analysis of secondary data. The MRC has also conducted a comprehensive and independent 10-year evaluation of MRC Translation Research 2008-2018 which includes outputs and impacts of the DPFS and CiC funding[29].

4.1 Project portfolio

Between 2012 and 2015, 73 projects were awarded funding through the DPFS, with an overall funding commitment of £61m to 2019. The portfolio of projects funded involved an emphasis on the development of novel therapeutics (around 70 percent of projects), including medical devices and psychological and behavioural therapies. A large share of the portfolio was focused on less traditional forms of drugs and therapies, with 19 percent of projects involving development of cellular and gene therapies, 14 percent on protein or peptide-based drugs, and 11 percent on antibodies. Projects involving a focus on medical devices, digital health, or psychological therapies were less well represented in the project portfolio.

It is important to note that while the scale and duration of DPFS projects funded vary by their starting point on the development pathway (72 percent were at preclinical stages of development and 28 percent at clinical stages), many of the projects funded begin at later stages than CiC projects and require more time and resources to deliver[30]. Only 30 of 73 projects funded were due to have completed at the time the survey research was undertaken in early 2018, and 12 of these were due to complete in the latter half of 2017. The long-term impacts of interest will generally depend on the ability of the PI to obtain follow-on funding following the conclusion of the project, and there was a limit to how far it is possible to observe these longer-term outcomes of interest.

Many projects were still in data collection stages at the time of research. As research teams often require time after the grant has come to an end to prepare their analyses, few had reached the stage at they could publish core findings, secure follow on funding, or exploit technologies under development. As such, the focus of this section is on how far DPFS enabled research teams to progress their work programmes more rapidly than they otherwise would have done and early signals of likely impact in terms of progression of the underlying technology or translational concept.

[29] The report can be downloaded at: https://mrc.ukri.org/publications/browse/10-year-translational-research-evaluation-report-2019/

[30] An average award size of £835,000 – more than 10 times the size of a typical CiC project.

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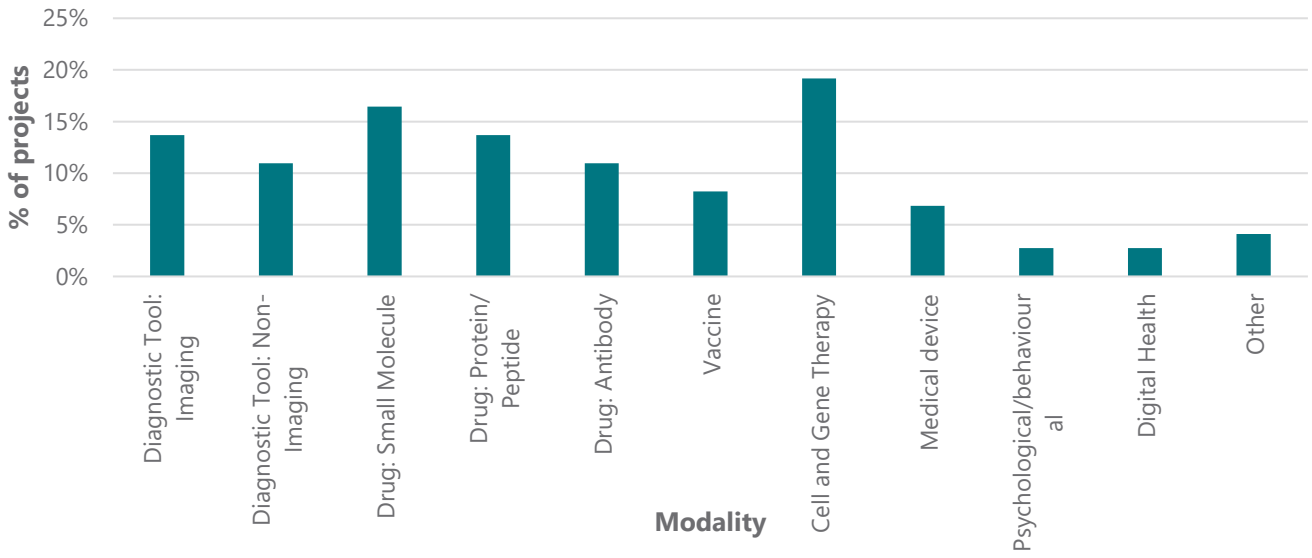
Figure 4.1: DPFS projects funded between 2012 and 2015 by modality

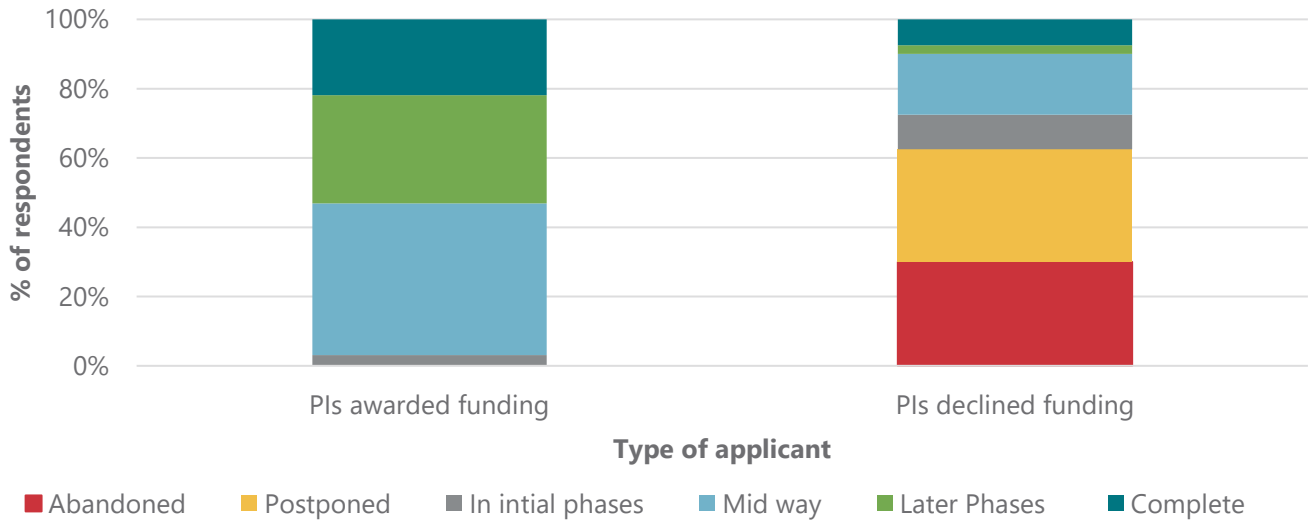


Source: MRC monitoring information

4.2 Project status

DPFS funding had a substantial effect on the ability of research teams to progress their underlying research programmes. The figure below compares the status of DPFS funded projects in 2018 to a comparison group of projects that were declined funding. While most of DPFS projects were at advanced stages of completion in 2018, a high share of those put forward by declined applicants had been abandoned, postponed, or remained at the initial stages (over 70 percent). Some care should be taken in interpreting these comparisons, as the survey covered both 'fundable' and 'non-fundable' proposals. Members of the latter group may not have been candidates for progression if there were flaws in the underlying scientific or proposed research design, and basic comparisons could overstate the impact of the programme (the issue of 'selection bias' is discussed in more detail in Annex A).

Figure 4.2: Status of DPFS projects in 2018 in comparison to unfunded applications



Source: Survey of BMC applicants, 2018

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The findings indicate that the DPFS occupies a comparatively unique position in the funding landscape and many PIs may have found it challenging to progress preclinical and early clinical translational research programmes in its absence. As illustrated in the following figure[31], 22 percent of unfunded PIs progressed their proposed research programme without making any compromises with respect to its scale or ambition, and a further 30 percent moved forward by reducing the scope or scale of the project. Findings from the CiC programme highlighted that this funding is strengthening the pipeline of ideas suitable for DPFS support. This is likely to continue to increase high quality competition for DPFS funding, and raises possible concerns regarding how far high quality, fundable, but unfunded DPFS proposals will be able to progress.

The two case studies of unfunded projects provide some illustration of how declined applicants were forced to adjust their plans. In one case, a team developing a novel anticoagulant secured a charitable grant at 10 percent of the value of the grant requested from DPFS. This allowed them to collect additional proof of concept data but they were forced to abandon plans to complete toxicology testing. In the second, the UK based research team was working with a US based radiochemist. The US based collaborator obtained further funding with a Chinese research group in response to being declined for DPFS funding. In this case, the underlying translational concept reportedly progressed to clinical trials, though the interviewee noted that there were some doubts as to whether the regulatory regime was sufficiently rigorous to meet the standards required by the global pharmaceutical industry (constraining the scope of its potential commercial application). Clearly, it is difficult to judge whether these projects had sufficient potential or data to justify the scale of funding sought, but these examples do illustrate that there are few straightforward alternatives to research teams to apply for a similar funding package.

Figure 4.3: Progression of unfunded DPFS projects

Source: Survey of BMC applicants, Ipsos MORI

[31] Note that this covers both PIs submitting both fundable and unfundable proposals.

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4.3 Project delivery, results, and outputs

4.3.1 Project delivery issues

Although the scientific results of the projects appear to be promising based on the evidence available at the time of the evaluation, the case study research did highlight several obstacles encountered by research teams that have worked to extend the timelines associated with the projects:

- Compound screening: One research team's project was delayed by a need to screen a large number of additional compounds to identify potential candidates that were active against the parasitic worms being targeted by the project.
- Regulatory approvals: One research team highlighted some of the complexities in identifying an appropriate animal model of the disease being targeted by the project, which resulted in repeated consultations with regulatory authorities to aid the decision-making process.
- Validation: Initial results were not always clear, and in some cases required additional validation tests to reach the required level of confidence. For example, one project required an additional six months of tests to build up clear evidence as to how the compounds under investigation affected the parasite being targeted.
- Suppliers: The case studies also indicated that price of CRO/CMO services was a significant consideration in the selection of suppliers, with some teams willing to trade-off quality of service against cost considerations (with interviews highlighting that it was difficult to obtain small quantities of proteins, cells, or molecular compounds at low costs, reflecting the underlying economics of the manufacturing process). One research team reported that this decision resulted in both time and cost overruns when a need for additional manufacturing processes to remove waste product generated in the process of synthesising the compound was identified.

It could be argued that the types of obstacle encountered were largely foreseeable at the beginning of the project, and may been avoided with more rigorous attention to risk management. However, the challenges encountered did not appear to cause PIs challenges in meeting the objectives of their MRC grants, though some had implications for the viability of follow-on research.

4.3.2 Emerging findings

While many projects were in advanced stages of completion at the time of the research, the majority were not at the point at which the full set of results were available, and it was too early to judge how far the portfolio of projects confirmed their initial hypotheses. However, DPFS projects are monitored based on the achievement of interim milestones (and can be terminated if these milestones are not met). Monitoring information suggested that of the 73 projects funded, 57 percent had passed all clinical milestones at the time of this review, while 16 had not passed at least one milestone.

More broadly, respondents to the survey were asked to report how far the findings of the project to date support the initial scientific hypotheses and whether emerging findings raised any concerns with respect to safety, efficacy, or other aspects that could influence commercial potential or clinical uptake. Overall, 63 percent of PIs awarded DPFS grants reported that results to date were supportive of the initial hypothesis, 31 percent reported that it was too early to judge, and three percent reported that the results were not supportive (note that these figures are self-reported and challenging to validate until the

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core manuscripts have been published). The most commonly reported concerns related to possible risk associated with the efficacy of the technology[32] (16 percent of PIs) and the scale of future development costs (16 percent of PIs).

4.3.3 Project outputs

In terms of outputs emerging from the project portfolio at the time of the evaluation:

- **Publications:** Researchfish data suggests that 662 journal articles have been attributed to 58 projects funded through the DPFS (implying around 78 percent of projects led to at least one journal article). There are some questions, however, as to the degree to which those publications can be directly attributed to the projects and the extent to which they describe the core results of the projects funded. For example, the case study evidence suggested that the publications produced at the time of the evaluation tended to relate to the results of early milestones in the project lifecycle, and research teams were either still in the process of analysing the main sets of data gathered or that the key manuscripts were in the peer review process. The publications were largely published between 2015 and 2017, which is too recent for meaningful analysis of citation patterns.

- **Intellectual property:** The results of the survey suggested that over half of those awarded funding had obtained background intellectual property rights before the projects. Around 20 percent of PIs responding to the survey indicated that they had made new applications for intellectual property protection in connection with the results of the project. This aligned with monitoring information collected by the MRC through the Researchfish monitoring system, which suggested that PIs had made 14 patent applications. Details of these of these patents were linked to the Espacenet patent portal, which indicated that half of these applications made no citations to 'prior art,' suggesting a level of novelty. The patent applications were made too recently to draw any meaningful conclusions around knowledge spill-overs that may be visible in citation patterns. The case studies did not highlight any examples of projects whose further development was blocked (or options for future exploitation constrained) by intellectual property held by external parties. This may be related to considerations made by the DPFS panel in terms of the research team's freedom to operate, though one respondent did note the role of the MRC Industry Collaboration Agreement (MICA) in preserving the freedom of the academic team.

4.4 Progression through the development pathway

To understand the level of translational progress that had been made by applicants since they applied for funding, respondents to the survey were asked to categorise the starting point of the project and its progression by 2018 against the Technology Readiness Levels scale[33]. This nine-point scale provides a description of the key milestones in the translational pathway. The figure below shows the distribution of the projects supported by the programme against the scale before the application for funding was made, its status in 2018, and compares the average level of progress made by those awarded funding and those that were declined. The figure suggests that PIs awarded funding progressed more rapidly (on average) than those not awarded funding (with declined applicants making little forward progress). Projects starting at later stages appeared to advance by fewer stages, though this will be linked to the more significant costs and timescales associated with clinical research activity.

[32] The degree to which the technology under investigation was likely to deliver its expected therapeutic benefits.

[33] Using a version of the scale specifically adapted for the development of small molecule pharmaceuticals, biologics, vaccines, and medical devices.

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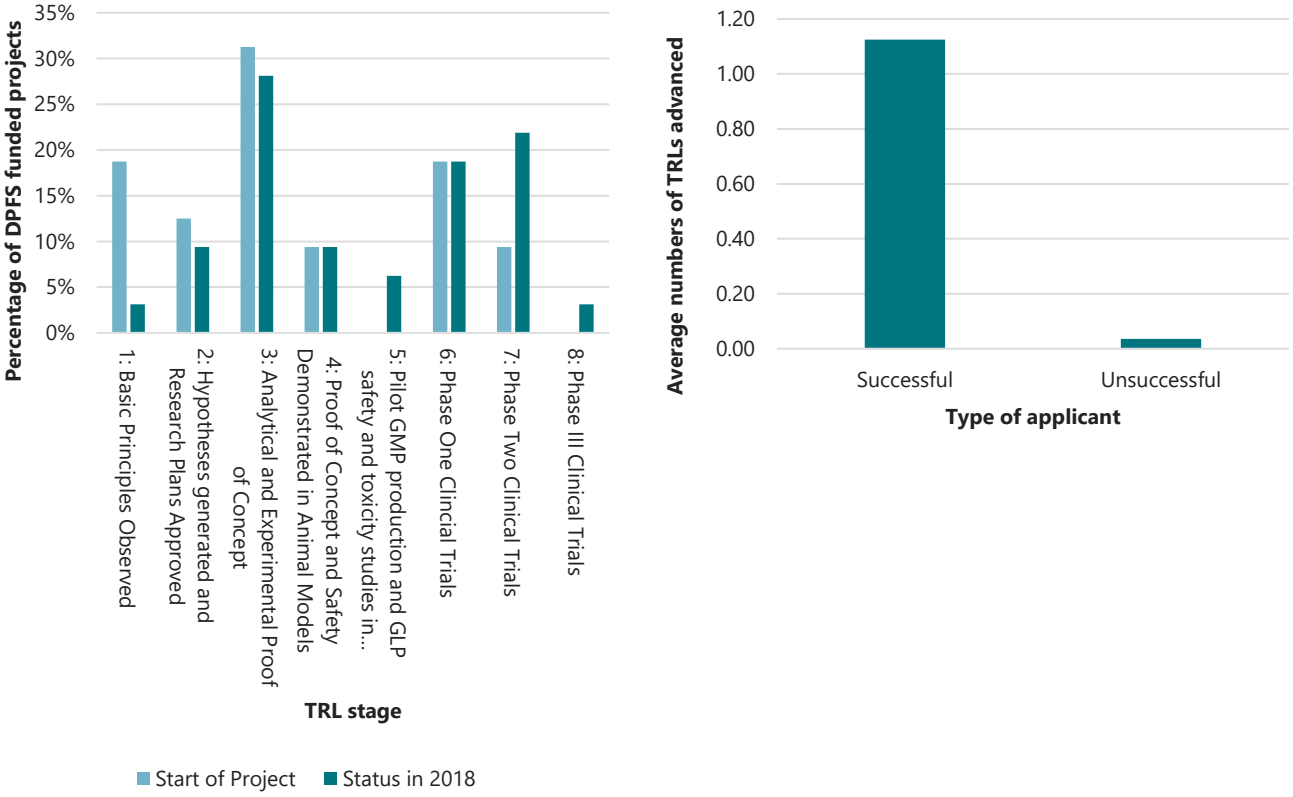
Econometric analyses of the survey results were completed to more clearly determine the causal role of the programme in accelerating the development of projects (details of which are set out in Annex A). This involved comparing successful and unsuccessful applicants for funding, while controlling for their pre-application characteristics and other possible confounding factors including the underlying quality of the proposal[34]. These analyses suggested that the DPFS had a significant impact on the progress made through the development pathway, suggesting that projects awarded funding progressed 0.6 to 0.8 to TRL stages further than they would have otherwise done. A simple comparison between the two groups suggests that projects awarded funding moved 1.1 TRL stages further than unfunded proposals, illustrating that while comparisons that do not control for proposal quality overstate the impact of DPFS funding, the programme nevertheless had a significant effect on the ability of the PI to move forward with their work programme.

Figure 4.4: Progression through the development pathway since application, DPFS projects



Source: Survey of BMC applicants. Figures are unweighted/.

4.5 Collaboration

All projects funded through the DPFS were collaborative in nature, with PIs typically working with a variety of Co-Investigators within and outside of their institutions. On average, there were 4.8 PIs and Co-Investigators named on DPFS applications. Seventy-nine percent of projects were interdisciplinary in nature, involving Co-Is from different academic fields[35] (frequently clinical scientists, but also academics from different areas of science such as physics), while 58 percent of projects involved

[34] Including the starting TRL level of the project, the broad modality of the underlying technology, the years elapsing since the application was submitted, the size of the research group from which the project was led, and the score awarded by the DPFS or MAC panels. The models also allowed for unobserved differences between PIs, projects and institutions that do not change over time.

[35] As inferred from their home department.

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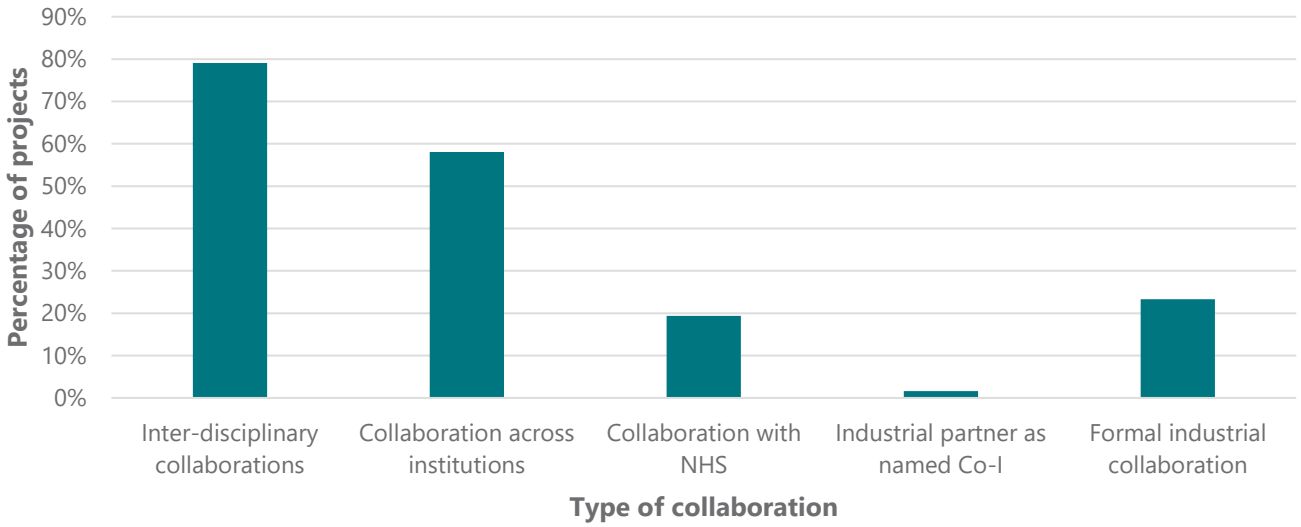
collaboration across different institutions, and 19 percent involved collaboration with researchers based within the NHS. An overview of these collaborative patterns is provided in the following figure.

Seventeen projects (23 percent) involved a formal collaboration with an industrial partner. This may be due to the early stage nature of many DPFS projects, and that public funding is needed to de-risk a project to the point at which industry can engage. However, the case studies also indicate that these figures may mask the true level of industrial engagement in projects – industrial organisations were often taking an active interest in the results being produced even where they had not committed specific resources to the delivery of the project.

Figure 4.5: Overview of collaborative patterns in DPFS projects funded between 2012 and 2015



Source: MRC monitoring information

4.5.2 Novelty of collaborative relationships

Respondents to the survey were asked to report the extent to which projects had involved new collaborations with external parties, and around 43 percent of PIs awarded DPFS grants reported that the project resulted in novel collaborations. Of these, 93 percent reported that the project resulted in novel collaborations with other academic institutions, and 21 percent reported novel collaborations with industrial partners. A similar proportion of unsuccessful applicants reported the project resulted in new collaborations with external parties, suggesting that new relationships are partly crystallised by the process of assembling an application rather than as a direct consequence of the grant. This is supported by the case studies, which did not signal any major additions to the collaborations formed to deliver the projects, though new relationships had begun to emerge towards the end of projects.

4.5.3 Benefits of collaboration

Respondents were also asked to report the main benefits of working in collaboration. The most frequently reported outcome was that the team could develop an enhanced understanding of the basic scientific principles underlying the project, which is likely connected to the high rates of interdisciplinary working observed in the research teams receiving DPFS funding.

The second most frequently reported outcome was an improvement in skills in planning and developing projects. The focus on project management may have been driven by MRC's requirement for milestone monitoring for DPFS projects, which represents a departure from the way in which many academic research projects are delivered. However, there were signals

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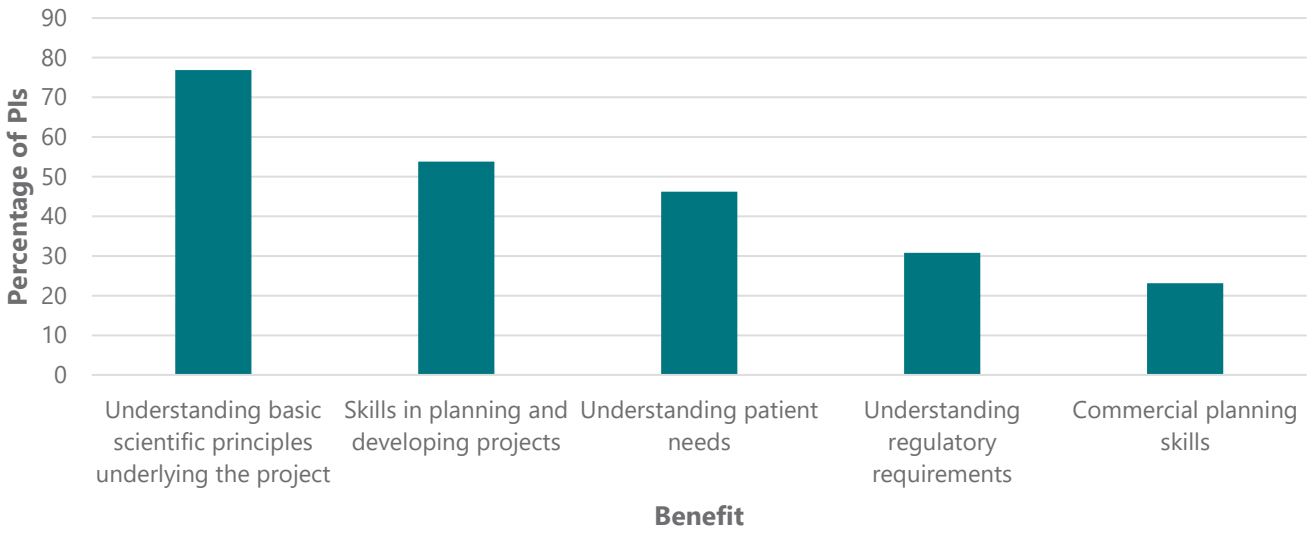
in the case study interviews that the process of delivering the project may have had lasting impacts on the skills, confidence and capability of researchers to engage effectively with translational research (with effects that extended beyond those directly involved). For example, one respondent indicated that they had made several key hires because of the project; these recruits had been retained by the institution to offer their experience to other projects. Another reported that the DPFS project led to more commercially minded approaches within the institution and encouraged the development of stronger support structures for translational researchers.

Although improvements in commercial planning skills were least frequently reported by PIs, the case studies also highlighted a perception that involvement in DPFS projects helped instil a stronger commercial mindset amongst academic researchers. For example, one PI claimed that they had observed other academics beginning to consider the 'value proposition' that might be associated with innovations and seek advice on how to effectively develop applications for translational funding (an effect that was not limited to the researchers involved in the delivery of the project).

Additionally, there were reported benefits in that the collaborations have led onto other research projects. One PI indicated that the working relationships formed through the project had led onto an application to fund an early stage malaria treatment drug discovery project, which would not have been possible without the relationships formed through the DPFS grant. Another indicated that the process of successfully delivering a translational research grants produced 'halo' effects, in that by demonstrating that the institution could successfully manage a clinical research project with an industrial partner, they had attracted interest from large pharmaceutical companies to deliver contract research project (around £850k in contract research income over two years was reported by the PI).

Figure 4.6: Reported benefits of collaboration



Source: Survey of BMC applicants. Figures are unweighted.

4.5.4 Uncertainty

The case studies also highlighted some uncertainties attached to collaboration, and the viability of future development work may be tied to changes in the strategies or priorities of partners. One research group reported that the exploitation route anticipated at the start of the project (in which the future development work would be funded by an industrial collaborator under a licensing agreement) had been put at risk by changes in corporate priorities that reduced interest in the technology

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under investigation. In this case, other commercialisation routes – including entering a licensing agreement with other commercial partners or establishing a spin-out - were potentially open to the research team as they held the relevant IP assets.

However, another team were working with a CMO to produce the small molecule being tested, which led to the subcontractor acquiring tacit knowledge regarding the manufacturing process that was fundamental to the efficient production of the material. The results of the project did not demonstrate the efficacy of the product, and the team were forced to revise their hypotheses. While the team reportedly found a solution to the problems encountered, the CMO had since adjusted its strategy and no longer produces small quantities of compounds for the purposes of research activity. The team are reluctant to incur equivalent 'learning curve' costs with another supplier and are unlikely to pursue the project further. This indicates that considerations regarding the robustness of future project delivery to supply chain risk are potentially of considerable importance in preserving options to pursue further development. It may be helpful to for the MRC to consider requesting applicants to describe in their application the possible threats to the onward development of the project beyond the lifetime of the grant and how they intend to manage those risks.

4.6 Follow-on funding

It is important to note that much of these advances described in section 4.4 were achieved within the grants awarded by the MRC. Research groups will need to secure follow-on funding from public, charitable or industrial sources to enable onward progression through the translational pathway. A high share of PIs funded through the programme (84 percent) reported that they intended to continue the development of the underlying translational concept beyond the lifetime of the grant. Around 53 percent reported that they had raised additional public or charitable grants since starting the project (an average of £1.1m in additional total grant funding was reported per PI), though this was both in connection with the underlying translational concept and other projects. As the research supporting this evaluation was completed as many projects were ending, it is difficult to reach firm conclusions as to how far (and how) research groups will continue development of the underlying assets.

The case studies suggested that in many cases, while plans for securing further funding were in place, these plans had not yet been executed and the research team may not always be directly involved in onward development. For example, one research group reported that they had secured additional funding to prepare the ground for clinical trials of a therapeutic for an orphan indication and were in discussions with a large pharmaceutical company with a philanthropic arm with respect to a licensing agreement. However, the team themselves reported that they did not have the confidence or experience needed to take the product through a clinical trials process.

Additionally, there were some uncertainties regarding how research teams may fund on-going development work, with the perceived risks largely stemming from the costs involved. One research team had produced promising data in relation to a protein based therapeutic for pulmonary arterial hypertension and was working in collaboration with an industrial partner with a potential interest in commercialising the technology. The collaborator had funded a third-party CRO to provide external validation of the results. While emerging findings from that study were reportedly promising, there remained some uncertainties as to whether the companies' investment committee would be willing to take the risk of embarking on a programme of Phase I & II clinical trials. Another team was forced to revise its starting hypotheses and had develop an alternative compound but was unsure as to whether they would pursue further funding applications owing to reluctance to duplicate costs already incurred in refining the original compound under investigation.

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4.7 Commercialisation

This final section examines the commercialisation plans of the research groups receiving funding through the DPFS. Respondents were asked to report how they intended to exploit the intellectual property developed through the project. Around two thirds intended to follow a commercial route to exploitation, and a third were exploring non-commercial routes. Licensing or sale of the underlying intellectual property was expected to be the dominant route to exploitation. Just over 25 percent of PIs expected to establish a spin-out to exploit the underlying technology. As noted, many of the projects were only at an advanced state of completion at the time of the research, and there had been limited opportunities for researchers to commercialise the underlying technologies.

Figure 4.7: Intended exploitation route, PIs funded through DPFS 2012 to 2015

Source: BMC, Applicant Survey, 2018

4.7.2 Licensing agreements

It has not been possible to collect systematic information on licensing agreements through the study. Only one PI reported that their institution had entered an agreement to license the underlying intellectual property generated through the project, while another reported they were in discussions. It is anticipated that a longer time horizon would be needed to demonstrate any impacts of the programme on licensing income, given the timing of the research feeding into this study.

4.7.3 Spin-outs

Despite the relative infancy of many PIs commercialisation plans, the results of the evaluation showed that the DPFS has already had a substantial impact on the UK biotechnology start-up landscape. To explore the effects of the programme in this area, a comprehensive database of spin-outs established by PIs making applications for grant funding between 2012 and 2015 was developed. This database was created by searching the Companies House register for companies established since 2012, where the PI was at some stage named as a Director and that the activities of the company could be connected to the details of the research funded through the DPFS grant. More detail on this analysis is set out in Annex C.

The data gathered showed that:

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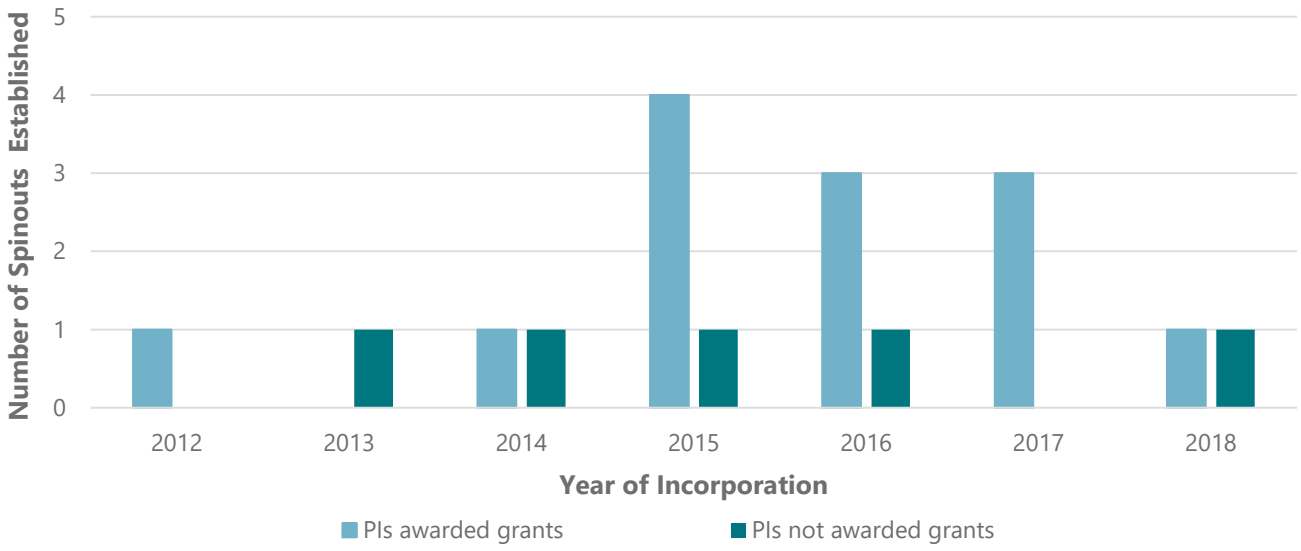
- **Spin-outs:** It was possible to identify 13 spin-outs emerging from the MRC grants awarded through the DPFS between 2012 and 2015. This is equivalent to around 18 percent of the PIs awarded funding through the programme, relative to four percent of those whose applications were declined. There was some overlap between the spin-outs emerging from the DPFS portfolio and those reported under CiC.

- **Year of incorporation:** Most spinouts established were incorporated between 2015 and 2017. As suggested by the survey of applicants, a significant share of PIs intend to establish a spin-out in the future, and it is unlikely that this represents the full scale of spin-out activity that may eventually emerge from the portfolio.

Figure 4.1: Number of spinouts established by year, PIs applying for MRC funding between 2012 and 2015



Source: MRC monitoring records, Companies House, Ipsos MORI analysis

- **Technology area:** Twelve of the thirteen companies established by PIs awarded grants were engaged in the development of novel therapeutics or vaccines. The businesses were typically exploring less established technology classes – such as gene therapies, immunotherapies, therapeutic vaccines or novel approaches to drug delivery (e.g. exosome based therapeutics). One digital health company emerged from the portfolio which was established as a social enterprise. The spinouts established by PIs not awarded funding showed a similar profile, including four therapy developers and one manufacturer of biologics.

- **Pipeline:** Most spinouts (where it was possible to determine) were multi-asset in nature, exploring several therapies at differing stages of development. One company (also originating in CiC funding) had acquired a portfolio of ex-vivo gene therapies from a large pharmaceutical company to augment its portfolio. Only one firm appeared to be pursuing a single candidate.

- **Clinical trials:** Data from the clinical trial registries suggested that three of the 13 spin-outs emerging from DPFS grants had entered clinical trials. This included Phase I/II trials of an AAV vector based influenza vaccine, Phase I/II trials of a range of gene therapies for ocular diseases and associated long-term follow-up studies (Achromatopsia, Leber Congenital Amaurosis, and X-linked Retinitis Pigmentosa), and Phase I/II trials for a gene therapy for ADA-SCID. All but one of these trials were being taken forward in the UK (though eight of these trials were being taken forward by a single company). None of the spin-outs established by those that applied but were not awarded a grant were at the stage of

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clinical trials (though one firm reported a study to gather tumour tissue samples to support the manufacturing processes for immunotherapies).

- **Investment:** Spin-outs emerging from research funded through the programme were considerably more successful in raising external investment than those established by PIs that applied for funding but were not awarded grants. Analysis of the share premium accounts reported in Companies House filings suggest that those benefitting from grant funding raised an average of £25.9m (a total of £233m), relative to £2.5m amongst that did not. These figures are accurate up to 2017, but do not capture significant recent funding rounds (including an IPO). More up to date figures from Pitchbook suggest that spin-outs emerging from research funded through the programme raised an average of £88m in equity investment (£0.5bn in total), with the caveat that data was not available for every firm. A large share of the overall investment raised was secured by a single firm which raised £371m in an IPO in late 2018 (the total excluding this firm was £158m, or an average of £26m).

- **Employment and R&D spending:** The spin-outs collectively employed 118 workers in 2018 and were twice the size of those that were established by those that were not awarded grants. It is unknown what share of these workers are involved in R&D occupations, as the companies involved have not disclosed this information in their accounts. Assuming a similar level of R&D spending per worker as those supported by Innovate UK (£182,000), allowing for the average age of the spin-outs established (2.4 years), and a share of R&D workers in overall employment of 50 to 100 percent, the total R&D spending of the spin-outs established by 2018 is estimated at £26m to £51m.

- **Firm valuations:** The total valuation of the spin-outs (where data was available) emerging from the DPFS portfolio was £1.3bn. Again, a large component of this arose from a single firm, and excluding this company, the total value of the portfolio was £263m.

- **Effect of DPFS funding:** A series of econometric analyses (described in Annex D) was undertaken seeking to provide more robust quantification of the effects involved by comparing marginal applicants. These findings also suggested that the MRC grants awarded through the programme had a significant causal role in the outcomes observed (with estimates suggesting that 40 to 80 percent of the spin-outs emerging from the programme were directly attributable to the grants).

- **Economic value:** Combining this result with the estimates of the total value of the portfolio would suggest a broad range for the total economic value attributable to the DPFS of £520m to £1.0bn if the outlying success is included in the calculation, and £105m to £210m if that firm is excluded. These figures do not include the value that might arise from licensing agreements, and clearly more time is needed to allow the portfolio of spin-outs to develop to understand the long-term impact of the DPFS. However, even at minimum, the additional economic value arising from the programme is likely to substantially exceed the costs of the programme. Allowing for uncertainties in attributability to MRC funding, the results imply a potential range for the benefit-to-cost ratio of £1.72 to £16.39 per £1 funding committed.

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Table 4.1: Comparison of spin-outs emerging from MRC funded grants awarded through the BMC/DPFS and those established by those applying for funding but not awarded a grant

Company	MRC funded spin-out	Spin-outs established by declined applicanrts
Average share premium account at most recent Companies House filing (£m)	23.3	2.5
Average number of employees (as reported in most recent Companies House filing)	14.8	7.3
Average number of clinical trials	0.9	0.0
Total equity investment raised (October 2018, Pitchbook)	529.2	17.1
Average valuation (enterprise value at September 2018 for listed companies, most recent pre-money valuation for businesses receiving VC or angel investment), £m	199.7	1.5

Source: Companies House, Pitchbook, and Pharmaprojects

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5 Innovate UK Grants

Key Findings:

- Businesses funded through the programme progressed more rapidly through the translational pathway than those that did not receive funding. It is estimated that **businesses moved forward 1.3 TRL stages further through the development pathway** than they would have done without funding,
- The awards made through the BMC to industry led projects had an enduring effect on R&D spending. It is estimated that the programme led to an increase in overall R&D spending of £248m to £350m by 2018. Allowing for public contributions of £141m, it is estimated the programme **levered an additional £0.76 to £1.48 of private R&D spending per £1 of public sector spending.** These findings suggest that the programme has been at least as effective (and potentially up to twice as effective) as R&D Tax Credits in leveraging private R&D spending.
- This was accompanied by a significant effect on number of R&D workers employed by these businesses. Grants increased employment of 11 to 15 percent over 3 to 5 years (net of deadweight), **equivalent to the creation of 234 to 330 jobs.**
- The results also showed that the BMC had a significant effect on the ability of businesses to leverage venture finance from the private sector. It is estimated that the 150 firms benefitting from the programme **raised between £563m and £710m in private investment as a direct result of the programme.** Allowing for all Innovate UK grants received by these businesses, the estimated leverage ratio was leverage ratios **between £3.99 and £4.99 per £1 of public spending.**
- Few applicants had launched products to market at the point of the evaluation. As such, the evaluation found no impacts on the turnover or productivity of those businesses that received support through the programme. Most applicants do not expect their research to lead to a new product until 2025 or beyond, through a high share of applicants plan to externalise the long-term exploitation of the technologies under development by selling the underlying intellectual property or reaching a licensing agreement with third parties. Given the high share of M&A activity led by overseas firms, there is a risk that the long-term exploitation of the intellectual property takes place overseas.
- A cost-benefit analysis of the grants awarded to firms by Innovate UK related the benefits of the programme embodied in the increase in the value of businesses supported and wage premia accruing to R&D workers suggested that the BMC also offered strong value for money with a **central estimate of the benefit to cost ratio (BCR) of £4.72 per £1 invested.** This substantially exceeds the hurdle rate of return typically applied in the approval of the Business Cases for these types of scheme.

This section examines the impact of grants awarded by Innovate UK to SMEs seeking to develop innovative therapeutics, diagnostics, or medical devices. This section draws heavily on a series of econometric analyses comparing businesses awarded funded to a comparison group of businesses that applied for funding but were declined, using a variety of administrative and secondary datasets to identify the impact of the grants on invest in, and the growth of, those firms

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receiving funding. This section also draws on evidence gathered through a survey of the businesses applying for grant funding and case studies of projects awarded funding.

5.1 Project portfolio

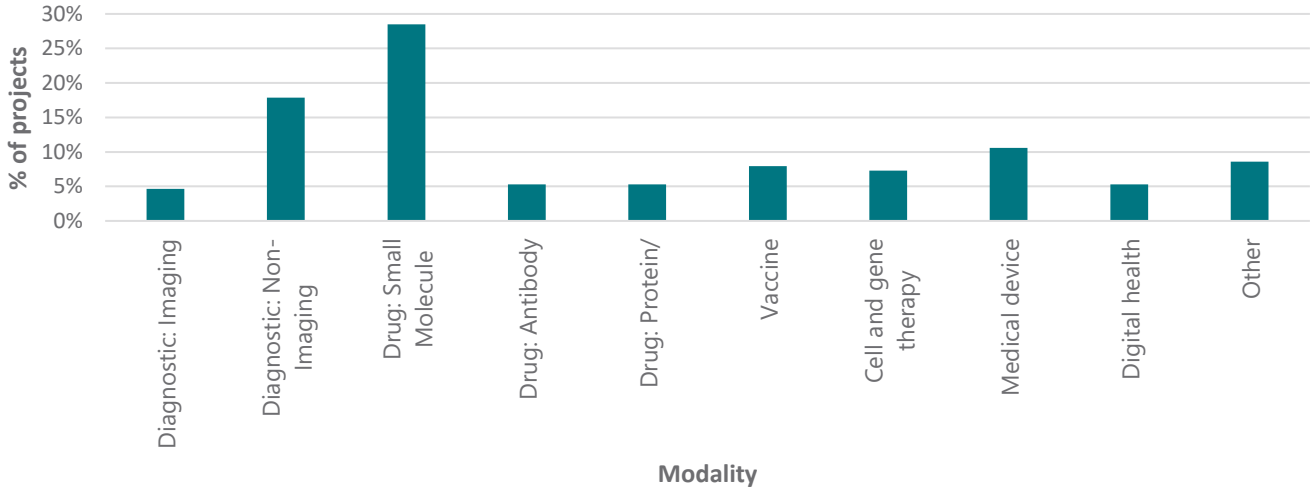
A total of 184 grants were awarded to SMEs through the BMC over eight competition rounds between 2012 and 2015, involving the commitment of £125m of public funds. This broke down into:

- Feasibility studies: Ninety-six grants for Feasibility Studies were awarded through the programme, involving a commitment of £13m of funding. These grants were awarded for early stage proof-of-concept research and were generally of smaller scale and shorter durations than other awards made for through the programme,
- Early stage awards: Fifty-two Early Stage awards were made through the programme, involving a funding commitment of £63m. These awards funded preclinical research up to the point of clinical trials.
- Late stage awards: The remaining funding (£49m) was allocated to 36 Late Stage awards. These awards aimed to fund clinical research activity, generally up to Phase II clinical trials (though there were some examples of Phase III trials being funded through the programme).

The figure below gives an overview of the projects funded by modality. The portfolio involved an emphasis on drug development, with 52 percent of projects involving the development of a drug, vaccine, or cell or gene therapy (with the majority focussed on small molecule pharmaceuticals (accounting for 54 percent of drug development projects). However, there was less emphasis on more novel areas of science such as cellular therapies or protein based therapeutics. Diagnostics accounted for 22 percent of the project portfolio, while medical devices and digital health accounted for a further 16 percent of the projects funded.

Collaboration was not a significant feature of BMC projects funded by Innovate UK. Twenty six percent of the projects funded by Innovate UK involved at least one collaborator (an average of 0.38 collaborators per project funded). Seventy five percent of these collaborations were with academic organisations, while 21 percent were with other firms or Research and Technology Organisations (e.g. Catapults).

Figure 5.1: Modality associated with Innovate UK funded BMC projects, 2012 to 2015



Source: Innovate UK Monitoring Information

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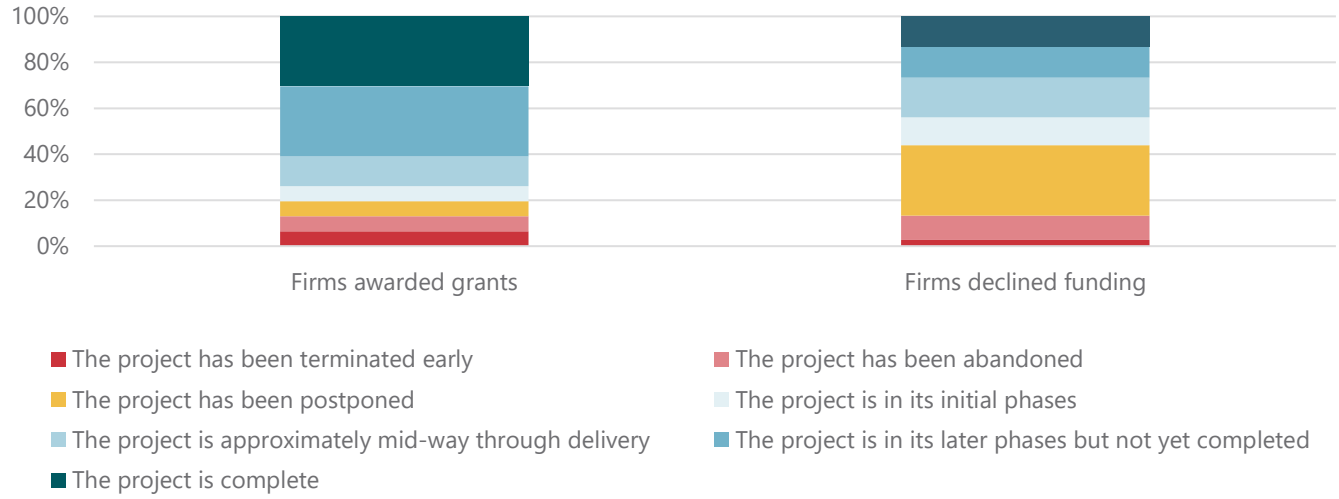
5.2 Project status

Respondents to the survey were asked to report the status of the project forming the focus of their application to the BMC as of 2018[36]. Businesses awarded grants had made more significant progress with their plans than those that were declined. Around 61 percent of firms awarded grants had either completed their projects or were at an advanced stage of completion, in comparison to 26 percent of those whose applications were declined. Equally, around 42 percent of businesses declined funding abandoned or postponed the project, relative to 20 percent of those awarded grants. This provides an indication that the grant was an important factor in enabling businesses to progress their R&D plans (though this could also reflect the effectiveness of the selection process in routing funding to the strongest business case).

Figure 4.2: Status of Innovate UK funded projects in 2018 in comparison to unfunded applications



Source: Survey of BMC applicants, 2018

5.3 Progression through the development pathway

As with applicants to the DPFS, to understand the level of progress made by applicants since they applied for funding, respondents to the survey were asked to categorise the starting point of the project and its progression by 2018 against the Technology Readiness Levels scale[37]. This nine-point scale provides a description of the key milestones in the translational pathway. The figure below shows the distribution of the projects supported by the programme against the scale before and after funding. The figure illustrates that in general terms projects advanced through the development pathway, and on average progressed around 2.0 TRL stages since the funding was awarded.

[36] Note that these figures are self-reported and may differ from Innovate UK monitoring records.

[37] Using a version of the scale specifically adapted for the development of small molecule pharmaceuticals, biologics, vaccines, and medical devices.

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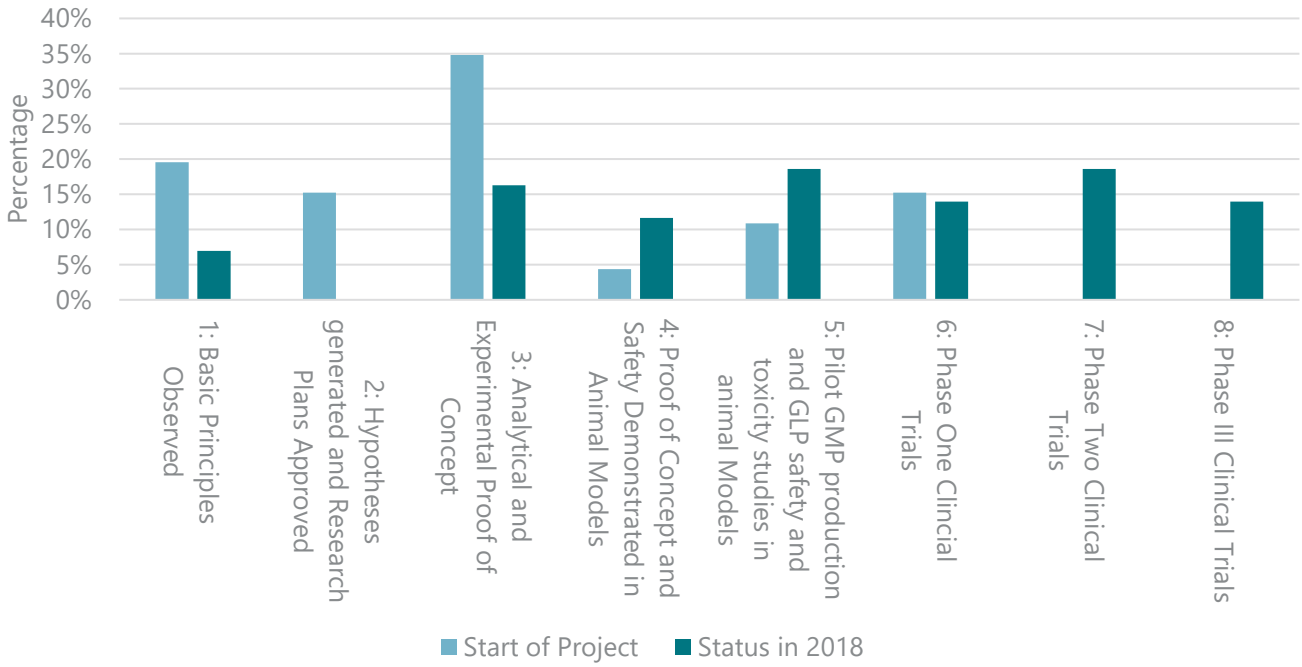
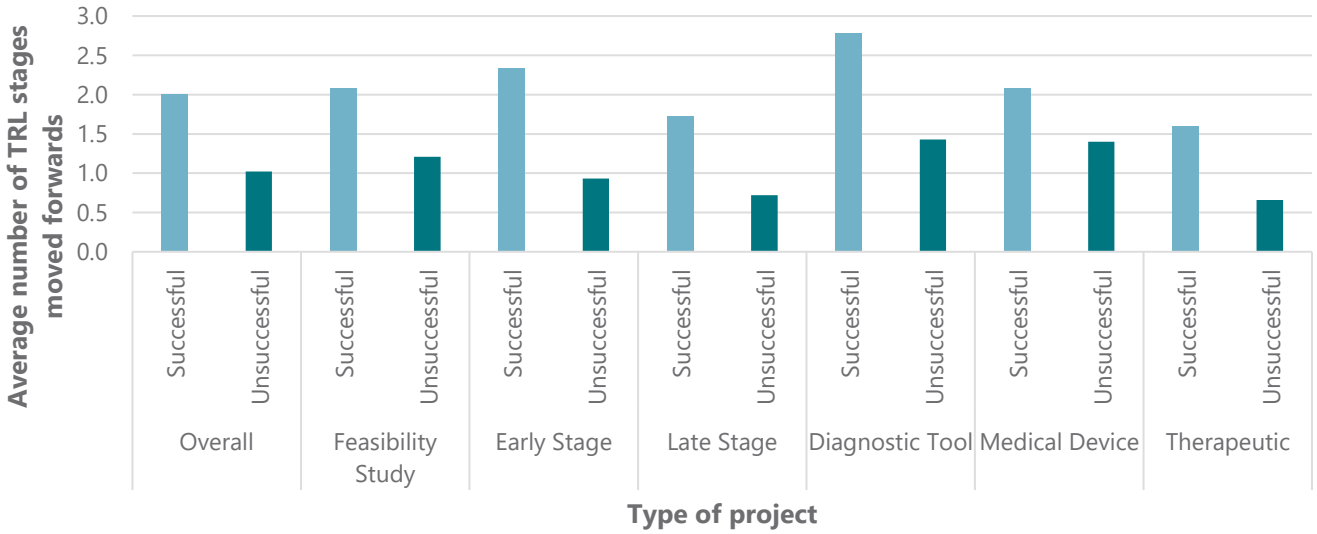
Figure 5.2: Progression through the development pathway since application, funded projects



Source: Survey of BMC applicants. Figures are unweighted.

The following figure illustrates the average number of TRL stages progressed by those awarded funding and those that were declined. Successful applicants progressed more rapidly (on average) than those not awarded funding regardless of the type of award (who on average moved forwards 1.0 TRL stage). These differences were significant at the overall level, though sample sizes were too small at the level of the type of award or modality to elicit significant differences between groups, and the comparisons provided in the following figure are indicative.

Figure 5.3: TRL stages progressed by 2018, by type of award, modality and success in the application process



Source: BMC applicant survey, 2018. Note that only differences in overall terms are statistically significant at the 95 percent level. Sample sizes too small at the level of the award or modality to draw conclusions but comparisons are provided for illustrative purposes.

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A series set of econometric analyses of the survey results were completed to explore the causal role of the programme in accelerating the development of projects. This involved comparing successful and unsuccessful applicants for funding, while controlling for their pre-application characteristic and other possible confounding factors. Further details are set out in detail Annex A. These analyses suggested:

- The awards made by Innovate UK has had a significant impact on the progress made through the development pathway by project teams following their application for funding. Findings indicated that on average, projects funded through the programme progressed 1.3 TRL stages further than they would have otherwise done.

- The acceleration effect was larger for early and late stage awards. There was no robust evidence that awards for Feasibility Studies had an impact on progression. As noted in the introduction, coverage of the population was low, raising the risk of non-response bias in these findings and it is challenging to draw firm conclusions.

5.4 Challenges encountered

The survey of respondents also explored the broad challenges encountered by applicants for funding:

- Reasons for termination: The main reason for terminating projects given by those applicants whose funding application was declined was related to difficulties securing finance (offered by 50 percent of those abandoning projects). Those awarded funding tended to suggest that they terminated the project because they failed to meet preclinical milestones. No respondents suggested that commercial factors, such as the emergence of competitor with a superior product or concerns about the eventual size of the market, were a significant factor in project termination.

- Results to date: No respondents that took their project forward suggested the results emerging from their programme activity did not support the underlying scientific hypotheses[38] (17 percent reported it was too early to say). However, a number flagged possible threats to the future development of the technology that were primarily non-technical in nature. The most prominent of these concerns were issues relating to the future revenues that might be generated by the product and potential future development costs (both flagged by around a fifth of respondents). There were no material differences between those awarded funding and those that were not in this respect.

Further evidence was generated from case studies of a mixture of both successful and unsuccessful applicants to the programme. These highlighted a combination of issues that were common across multiple projects:

- Access to finance: This issue affected both applicants whose funding application was declined as well as successful applicants who felt their project had been a technical success, but which could be progressed further with additional funding. For example, one SME receiving funding had developed a new pump technology which performed better than expected and the project completed as planned. However, further development had since put on hold as further clinical trials were viewed as carrying significant risks, deterring VC funds. This was echoed by another applicant that found it challenging to reach an agreement on terms with VC funds seeking minimal risk, a three- to-five-year time frame for an exit. Some applicants also suggested that they had struggled to convince investors of the commercial potential of their technology. These views were self-reported by the applicants who may have valued the technologies in question more highly than external observers asked to provide risk finance. The findings below also indicate that accessing follow-on funding did not appear to be a systematic problem for those awarded grants.

[38] Note that this was the self-reported view of the project lead, which is difficult to validate.

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- Complementary technology or infrastructure: Absence of complementary technology was an important factor in at least two of the case study projects. One applicant required significant further funding to obtain more clinical data to enable their technology (a biomarker for Alzheimer's) to be commercialised. However, investors raised queries regarding the commercial value of the technology on the basis that there were no effective treatments for this type of neurogenerative disease.

- Efficacy: The primary technical reason for stalled progression or cancelled projects was lack of efficacy (i.e. the product did not produce its intended therapeutic benefits), highlighting the risky nature of R&D in the sector even where the candidate and the disease pathway were (reportedly) well characterised.

The examples do highlight that in some cases, weaknesses in the commercial case for the technology were a factor in constraining onward development. While the overall rate of return attained indicates that this is not a systematic problem, it does potentially highlight a possible role for more detailed scrutiny of the economic case for investment in maximising the value for money associated with the programme (an issue identified in previous process evaluation study)

5.5 R&D activity

5.5.1 Private R&D spending and employment

Two sources of information were used to explore how far the grants awarded through the programme led to an increase in R&D spending. Firstly, the survey of businesses applying for Innovate UK grants was used to explore the extent to which those benefitting from the programme had expanded their R&D spending and employment for a sample of applicants for funding through the programme: Information on overall employment across all applicants for funding was also available from the Business Structure Database, though this did not discriminate between R&D workers and other types of workers. Results across these two sources were triangulated to reach a view on the impact of the programme on overall R&D activity.

The survey of businesses indicated that:

- R&D spending: Both those awarded funding and those that were declined reported that they had significantly expanded their annual R&D spending since applying for grants. Successful applicants saw their average annual R&D spending rise by 93 percent (from £1.3m to £2.5m), while unsuccessful applicants saw their annual R&D spending expand by 79 percent (from £0.8m to £1.4m). This indicates that grants tended to be awarded to more established businesses with access to greater capital resources.

- R&D employment: Both groups of businesses also reported that they expanded their R&D employment. Successful applicants expanded their average employment by 63 percent (from an average of 7.7 workers to 12.4 workers), while unsuccessful applicants saw their employment rise by 47 percent from 5 to 7.4 workers).

Two sets of econometric analyses were completed (described in Annex A and Annex B) to explore the degree to which expansions in R&D activity could be attributed to grants awarded (using survey based and administrative data respectively). These analyses compared the performance of successful and unsuccessful applicants while controlling for their pre-application characteristics and other potential confounding factors:

- Survey based results: Analyses based on the data collected through the survey suggested the grants had a positive effect on R&D employment and expenditure amongst those receiving late stage awards (of the order of 40 percent), but were not statistically significant for other groups of businesses. The estimated impact on overall employment and R&D

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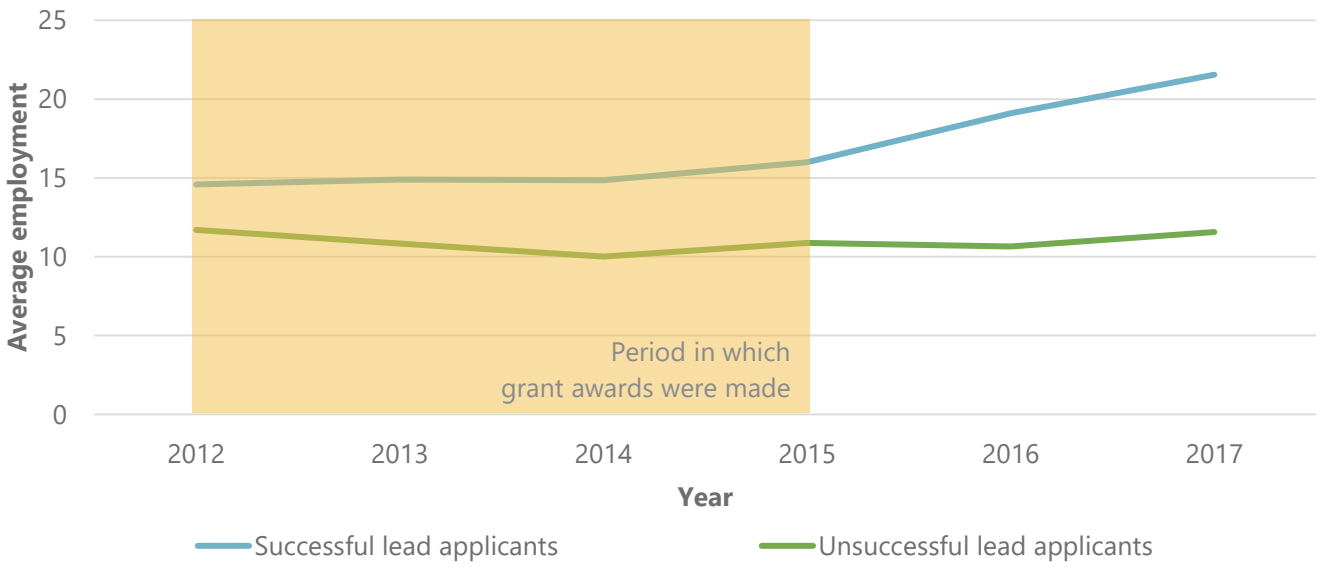
employment were broadly equivalent, suggesting the bulk of jobs created were in R&D occupations. However, the results were not conclusive and were not stable across different modelling approaches, likely due to the high level of variance in the underlying data and the comparatively small sample sizes available.

- Results based on administrative data: More robust results were obtained by linking details of all applicants (including collaborators and subcontractors) to administrative records of business level employment held with the Secure Research Service maintained by the Office for National Statistics. While this data did not provide data on R&D employment specifically, based on the findings from the analysis of the survey results and limited evidence of commercialisation of the underlying technologies, it was assumed that changes in overall employment were primarily driven by changes in levels of R&D activity. The figure below illustrates changes in employment amongst successful and unsuccessful lead applicants to the programme between 2012 and 2017 based on these administrative records:

  - Lead applicants: The average employment of lead applicants awarded grants grew by 48 percent from 14.6 to 21.5 workers by 2017, while remaining virtually unchanged amongst those that applied but were not awarded the grant (11.5 workers). These differences were significant at the 95 percent confidence level, with much of the employment growth amongst businesses awarded grants occurring after 2014. These patterns were broadly consistent with the findings of the survey, though there was a suggestion that the survey was biased towards larger businesses (possibly driven by the comparatively lower response rates amongst those applying for feasibility study awards).

  - All applicants: Data was also gathered on all businesses receiving funding through the programme (including collaborators and subcontractors). This larger group of businesses saw their average employment remain static between 2012 and 2017 (at 123 to 125 employees). These patterns were dominated by those businesses acting as subcontractors to lead applicants – which included large Contract Research Organisations (CROs) and Contract Manufacturing Organisations (CMOs) that were substantially larger than the small companies tending to take the lead role (average employment was almost 200 amongst subcontractors). These patterns may reflect stagnation in pharmaceutical R&D spending since 2012, which has remained comparatively static after a long period of expansion, or that applicants selected relatively stable suppliers that do not expand or contract to meet demand.

Figure 5.4: Average total employment 2012 to 2017, successful and unsuccessful lead applicants



Source: Business Structure Database, Office for National Statistics, Ipsos MORI analysis

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Econometric analyses using this more robust data (as described in detail in Annex B) yielded the following findings:

- Impact on employment: The BMC had an enduring effect on the number of workers employed by lead applicants receiving funding. Grants led to an increase in employment of 11 to 15 percent, and led to the creation of an additional 234 to 330 jobs (equivalent to 0.9 to 1.4 percent of total R&D employment in the pharmaceutical sector[39]). This figure is net of deadweight. As noted, the apparent effects of the programme employment are interpreted as a sign of greater levels of investment in R&D activity rather than the recruitment of production, commercial management, or sales and marketing staff.

- Crowding out: There is a possibility that additional demand for skilled labour placed pressure on wages, encouraging other businesses to scale back their R&D activities. However, broader trends in the life sciences sector – including falling R&D spending and wages for R&D workers[40] - suggests that this may not have been likely.

- Leverage of R&D spending: Assuming the additional jobs created are primarily in R&D occupations, it is estimated that the programme led to an increase in R&D spending of £248 to £350m by 2018 (based on average R&D spending per worker reported by businesses responding to the survey[41]). Allowing for public contributions of £141m[42], it is estimated that between £107m and £208m of this represents private spending on R&D. This implies the programme levered an additional £0.76 to £1.48 of private R&D spending per £1 of public sector spending. These findings suggest that the BMC has been at least as effective (and potentially up to twice as effective) as R&D Tax Credits in leveraging additional private R&D spending[43].

- Collaborators and suppliers: No effects were found on industrial collaborators or subcontractors. While the number of collaborators included in the analysis was too small to draw conclusions, these findings suggest that any multiplier effects resulting from additional R&D spending in the supply chain have likely been offset by crowding out of parallel R&D activity.

5.6 Leverage of private investment

This section considers the impact of the BMC in leveraging private investment into the biotechnology and medical technology sector between 2012 and 2018. This analysis is based largely on a dataset linking records of all successful and declined applicants scoring above 65 in the independent assessment process for BMC funding (286 businesses in total) to firm level records of investment activity collected by Pitchbook. Pitchbook tracks market data on angel investments, venture capital, private equity and mergers and acquisitions as available from press releases, regulatory filings, websites, and news articles. Further details of this analysis are set out in Annex C.

[39] 24,000 workers as estimated in the 2017 Business Expenditure on Research and Development survey by the Office for National Statistics. Other medical technologies are not reported as a discrete product group in the survey.

[40] BERD, Office for National Statistics.

[41] An estimate of the total R&D spending levered by the programme was derived by applying average R&D spending per R&D worker reported by successful applicants to the Biomedical Catalyst (£182,209) to the total number of R&D employment years associated with the jobs created (1,360 to 1,920). This value was broadly consistent with pharmaceutical sector averages in 2016 (£171,750).

[42] This includes grants awarded to beneficiaries of the programme after their Biomedical Catalyst award

[43] See Do Tax Incentives for Research Increase Firm Innovation? An RD Design for R&D. Dechezlepretre, Einio, Martin, Nyugen and Van Reenan. Centre for Economic Performance Discussion Paper No 1413. London School of Economics. 2016

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5.6.1 Equity investment in businesses supported by Innovate UK

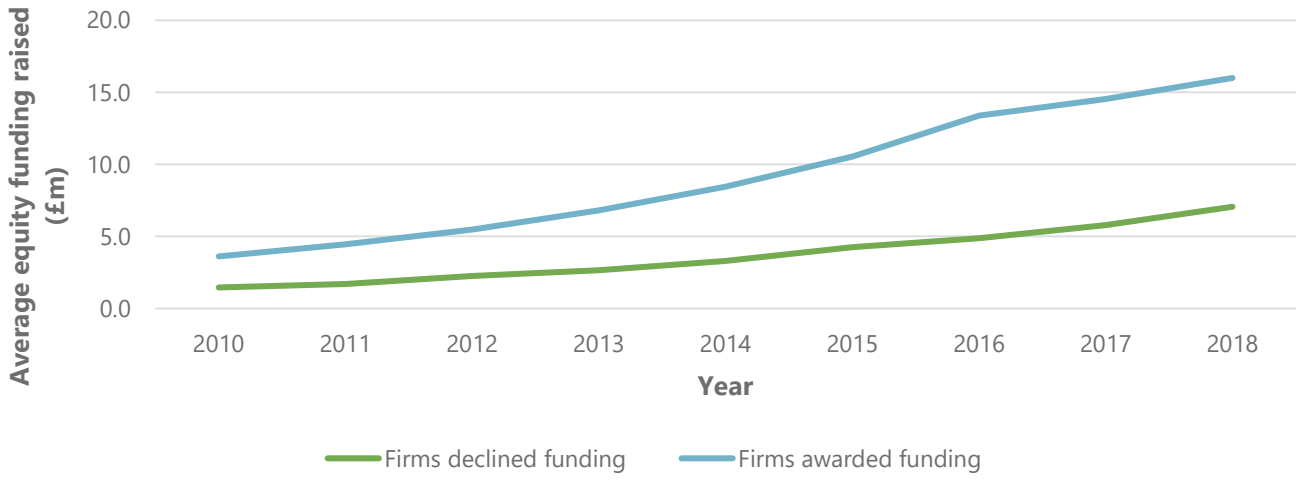
Based on data held within Pitchbook, 84 businesses (55 percent) supported raised additional funds after being awarded a grant:

- Equity investment: Overall, businesses raised a total of £1.3bn in equity investment over 133 funding rounds after they were awarded a grant[44] (an average of £8.8m per firm). This included a mix of angel investments, early and late stage investments by venture capital fund (VC funds), private equity investments, and initial and secondary public offerings. Around £440m of this was accounted for by two significant funding raisings by two companies. These deals involved a total of 118 new investors in the businesses concerned, of which 47 were domiciled overseas.

- Comparisons to unsuccessful applicants: Overall fundraising conditions in the life sciences sector also improved substantially between 2010 and 2018. This raises questions as to how far the grants awarded through the programme directly contributed to the funding raised, or whether the businesses concerned would have raised similar levels of investment as conditions improved. To offer some insight into this question, the figure below compares the average level of equity funding raised by businesses receiving grants through the programme to applicants that submitted a high scoring application (i.e. scored more than 65 in the assessment process) but were declined following the Funder's Panel. The figure illustrates that those businesses that were awarded a grant raised larger sums of funding over the period than the highest scoring declined applicants by 2018 (£16m in comparison to £7m).

- Distribution of success: The overall differences in investment raised by those awarded funded and those declined funding were to some extent driven by the top performers. The top 10 percent of funded firms (by total equity raised since applying for grant) saw their average level of investment attracted rise from on average of £20.1m to £106.4m between 2010 and 2018 (compared to £2.2m to £39.6m amongst the equivalent group of unsuccessful applicants). The next 10 to 60 percent of funded firms saw average levels of investment rise from £1.5m to £10.1m (compared to £0.8m to £4.6m amongst declined applicants), while the bottom 40 percent saw investment rise from £1.8m to £3.6m (£1.5m to £3.0m amongst declined applicants).

Figure 5.5: Average external investment raised (cumulative), successful and high scoring declined applicants to the Biomedical Catalyst, 2010 to 2018



Source: Pitchbook and Innovate UK monitoring information (150 firms awarded grants, and 134 declined applicants).

[44] For firms receiving multiple awards, this was calculated from the date of their first award.

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A series of econometric analyses comparing the funds raised by successful and declined applicants were completed to examine the causal effects of the programme in stimulating private investment (set out in Annex D):

- **Impact of the BMC on fundraising:** The results suggested that the BMC had a significant impact on the ability of businesses to leverage additional venture finance from the private sector in the medium term. It is estimated the 150 businesses benefitting from the programme raised between £563m and £710m in private investment as a direct result of the programme.

- **Cost-effectiveness:** The findings point to a leverage ratio of between £4.99 and £6.36 of private investment raised per £1 of Innovate UK grant spending through the programme. However, some businesses benefitting from the BMC also received grants awarded by Innovate UK through other programmes (though not necessarily for the same underlying project) which may have also contributed to these outcomes[45]. Allowing for this additional public spending reduces these leverage ratios to between £3.99 and £5.09 per £1 of public spending.

- **Benchmarking:** Even accounting for the totality of Innovate UK support for these companies, the programme appears to have proven an effective instrument for levering investment into the biomedical sector. Few past studies have explored the impact of R&D grants on equity financing, so it is difficult to benchmark the relative effectiveness of the programme[46].

- **Late and early stage awards:** Late stage awards accounted for two thirds of the overall impact, while one third of the impact was driven by early stage awards. Larger late stage awards appeared to be substantially more efficient as an instrument for leveraging private investment into beneficiary businesses. This may mirror the more intensive capital requirements of later stage R&D activity in the sector, and suggests public sector investment this stage can be particularly effective in de-risking projects from the point of view of investors.

- **Feasibility studies:** However, there was no robust evidence that funding for Feasibility Studies produced a long-term effect on private investment. It is possible that the relatively small size of feasibility study awards does not produce sufficient de-risking of the technology or balance sheets to leverage additional private funding (and potentially implying a need for continued public funding for these projects where proof of concept studies demonstrates the technical and/or commercial potential the underlying technology). Feasibility studies are also furthest from market, and it may be that it is too early to detect effects on private investment.

5.6.2 Mergers and acquisitions

In addition, 16 businesses were acquired after receiving a grant. These deals involved a further £1.8bn of investment (in four cases, the value of the deal was undisclosed), with three deals accounting for £1.5bn of the total. Of the £1.8bn, £430m represented future pay-outs contingent on the achievement of clinical milestones (though the size of upfront and contingent payments will not have always been disclosed). Thirteen of these businesses were acquired by overseas investors from North America (5, £433m), elsewhere in Europe (5, £977m), or Japan or China (3, £278m). Ten of these companies continued to maintain a UK presence in 2018 (i.e. employees had been retained within the business). While there were a relatively small number of acquisition deals recorded across the portfolio, a large share of these (over 80 percent) involved a transfer of

[45] Note that estimates of impact are driven by comparisons between successful and unsuccessful applicants for funding. As such, while the effects of interest are attributable to the grant, it is not possible to discriminate between effects that are driven directly by development of the assets being funded through the programme and indirect effects mediated by knowledge or skills that were acquired through the grant.

[46] The study 'Do R&D Subsidies Affect SMEs' Access to External Financing?,' Meuleman and Maeseneire, 2012, found that only grants for R&D awarded by the Belgian Government to start-ups had a positive effect on external equity funding (and did not provide leverage ratios against which these findings could be compared). No other studies examining this effect were found.

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ownership to overseas investors. This raises a possible risk that the intellectual property developed through the programme is ultimately exploited overseas, limiting the long term economic benefits of the programme to the UK (though clearly, the income raised represents a short-term gain for equity holders in the UK).

5.7 Exploitation outcomes

The sectors targeted by the BMC are characterised by long product development timescales. As illustrated in the preceding sections, the programme had a positive impact in accelerating the development of the technologies underlying the programme. However, few had progressed so far that they launched a new product to market. The figure below sets out expectations around the timeframes over which both industrial and academic applicants to the BMC expect to launch a new product to market based on responses to the survey:

- Product launches to date: Eleven percent of firms awarded grants had launched a new product to market by January 2018, with no statistically significant differences between those awarded a grant and those that were not. Secondary research into the nature of the products launched (details of 9 products were collected through the survey) suggested that these were either medical devices or diagnostic tests (7 and 2 respectively), in line with expectations that these types of product can be commercialised more rapidly than therapeutics.

- Expected product launches: As illustrated in the figure below, around 15 percent of successful applicants expected to launch a product within two years, 41 percent within a two to five-year timeframe, and 13 percent in five or more years. Those awarded grants either expected to commercialise their innovation more rapidly than unsuccessful applicants, and were less likely to have abandoned or terminated their projects.

- Nature of exploitation plans: Respondents were also asked to describe the nature of their exploitation plans. The most commonly reported expected commercialisation route was to license the underlying intellectual property to an external party (29 percent of firms awarded grants) while 16 percent intended to sell the intellectual property to a third party. This suggested a significant share will seek to externalise the risks and costs associated with commercialisation, again highlighting the potential risk that the intellectual property developed through the programme will eventually be exploited elsewhere. A further 27 percent reported an intention to develop a full production model (either vertically integrated or using contract manufacturing organisations). The remainder had either abandoned their technology or were not able describe their exploitation plans at this stage.

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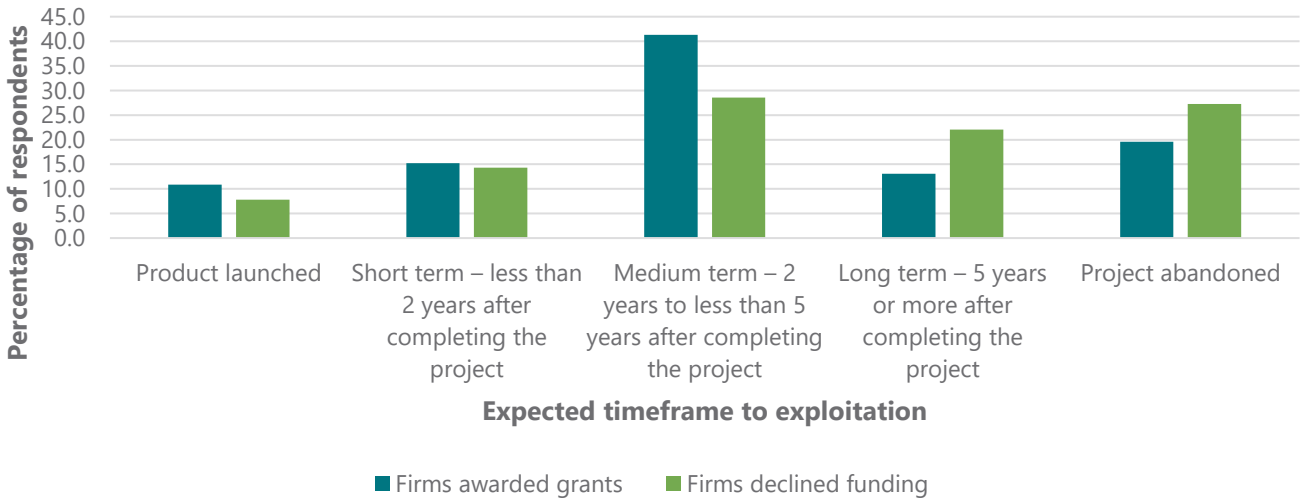
Figure 5.6: Timeframes to Exploitation – Successful and Unsuccessful Applicants to BMC



Source: Survey of BMC Applicants, January 2018. Base: 195 respondents.

5.8 Turnover and productivity impacts

The results of the evaluation did not suggest the programme led to significant effects on the turnover or productivity of businesses supported through the programme (see Annex C for more details of this analysis). This result is expected given the duration of product development cycles in the sector. It is also consistent with the findings emerging from the survey that showed that, while applicants have progressed development of biomedical technologies more rapidly as a result of the grant, few have launched a product to market. The survey also suggested that the prevalence of licensing agreements was comparatively limited: just 4 percent of firms awarded grants had managed to secure such an agreement by 2018, though a further 13 percent were in discussions to do so.

5.9 Cost Benefit Analysis

This section sets out the results of a cost-benefit analysis of the grants awarded by Innovate UK. A fuller description of the analysis, underlying theoretical framework, and supporting econometric analysis is set out in Annex E.

5.9.1 Impact on value of businesses supported by Innovate UK

There are several challenges involved in completing a cost-benefit of the programme, as its effect on output and productivity are only realised in the long term, outside the timeframes of the evaluation. While the programme had numerous positive effects in accelerating the development of biomedical technologies, there were no effects on turnover or Gross Value Added (GVA) as businesses have not reached the point at which they can launch new products to market.

The analysis sought to address this issue by focusing on changes in the valuations of businesses rather than the GVA based metrics more typically employed in the evaluation of innovation programmes. In perfect financial markets, the value of a business can be understood as a measure of market expectations of the net present value of its future profits, over and above the private returns that could be earned on investments in risk-free assets. This valuation should, in principle, account for the future commercial and technical risks associated with realising those profits, which in turn will partly reflect the nature of the potential (global) health benefits associated with the product. The preclinical and clinical development activity stimulated by the BMC – where findings justify continuation of the work programme - should lead to reductions in the risks

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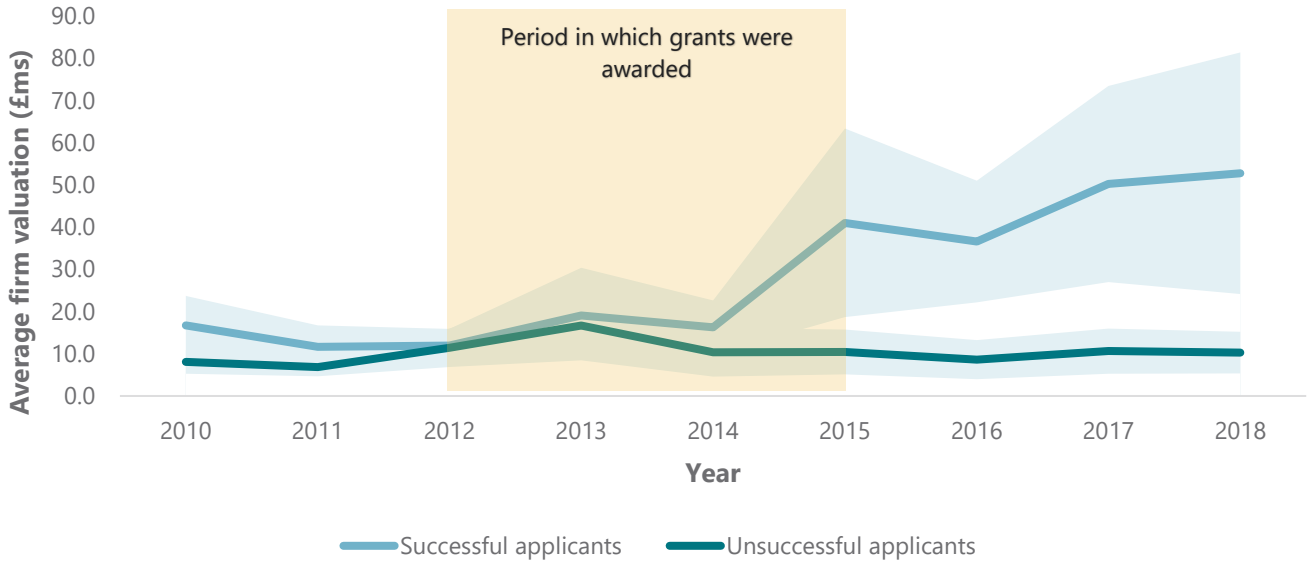
involved and produce an increase in the market value of the business. As such, the impact of the programme on the value of businesses provide a measure of benefit that is consistent with HM Treasury Green Book, notwithstanding the caveats highlighted in Annex E (and in particular, how far market prices accurately reflect long-run expectations of future profits).

The figure below shows the estimated average valuation of businesses that were successful in their application for BMC funding and those that applied but were not, based on valuations captured from Pitchbook. The figure suggests that the average values of successful and unsuccessful applicants[47] to the programme were broadly equivalent when the programme was launched in 2012 (at £11.4m to £11.9m). However, from 2015 onwards, the average value of successful applicants rose to just over £50m while remaining broadly unchanged amongst unsuccessful applicants. As illustrated in the figure below, the differences between the two groups are statistically significant. The underlying distributions were skewed in both cases by outlying successes and failures[48], and the median valuation of businesses awarded grants in 2018 was £5.3m compared to £1.3m for businesses whose application for funding was declined (compared to £4.7m and £3.9m in 2012 respectively[49]).

Figure 5.7: Average business valuations, 2010 to 2018, successful and unsuccessful applicants



Source: Pitchbook, Innovate UK monitoring information, Ipsos MORI analysis. Shaded area shows 95 percent confidence interval.

Two sets of econometric analyses were completed to provide an estimate of the impact of the programme on firm values:

- Longitudinal panel data: A first set of econometric analyses were completed using panel data on firm valuations collected through Pitchbook to identify the causal effect of the programme on the average of valuations of businesses (i.e. how far the changes observed above could be attributed to the grants[50]). These models suggested that each grant awarded through the programme led to an average effect on business values of £8.2m to £9.6m. The results are robust to

[47] Those scoring 65 or more in the independent assessment process.

[48] Where a business was dissolved, it was assumed to have zero market value.

[49] Note that each firm was only included in the sample from the point at which its value was first observed, so the baseline figures relate to a subset of the firms in the sample).

[50] Again, estimates of impact are driven by comparisons between successful and declined applicants for funding. While the impact can be attributed to the grant, it is not possible to discriminate between direct effects (i.e. effects driven by development of the underlying technology) and indirect effects (the translation of knowledge and skills acquired through the project to develop other assets or aspects of the operation of the firm).

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unobserved differences between businesses that do not change over time, but non-randomness in the data (as highlighted above) could lead to bias in the findings.

- Imputed values: The results above are subject to possible biases driven by the unobserved nature of the values of many businesses that applied for funding. A second set of analyses using the data gathered through the survey of applicants was completed to attempt to tackle this issue (technical details are provided in Annex E) by imputing the values of those businesses that did not receive equity investment. These analyses produced similar results, suggesting that the grants awarded through the programme led to an increase in the value of the business of approximately 51 percent, or £7.6m on average.

The estimated total impact of the programme the value of businesses supported is set out below.

Table 5.1: Estimated impact on business values, BMC awards made by Innovate UK

	Valuations based on Pitchbook (Low)	Valuations based on Pitchbook (High)	Valuations based on survey results
Average impact per grant / business (£m)	8.2	9.6	7.6
Total number of grants awarded / businesses receiving grants	184	184	150
Estimated impact on business values (£m)	1,509	1,766	1,140

Source: Ipsos MORI analysis

5.9.2 Leakage

Estimates of the impact of the programme on business values should be discounted to account for the share of the implied future profits that may accrue to investors overseas. Respondents to the survey of applicants were asked to report what share of their business was held by overseas investors before they applied to the programme. The results suggested that on average overseas investors held seven percent of the equity of businesses that received grants through the programme (weighted by employment). This result was used to estimate the net benefits of the programme.

5.9.3 Costs

Finally, as referenced above, the estimated impact of the awards made by Innovate UK on private R&D expenditure was £248m to £350m. This does not capture the costs incurred by Innovate UK in its administration of the programme, which could not be made available as the relevant expenditures are split across multiple teams, and the costs of individual competitions cannot be isolated. As such, the total costs involved may be understated at the margin. Research Councils UK financial statements[51] suggest that administration costs represent 2.6 percent of programme spending, which would imply the costs of administering the programme would be in the order of £3.2m (i.e. 0.9 to 1.3 percent of private costs) and would be insufficiently significant to materially affect the BCRs presented below. There is also an issue of grants awarded to these businesses prior to the launch of the programme. These costs have been treated as sunk and not included in the analysis, and it is assumed that these would have been capitalised into the baseline values of businesses in efficient markets.

[51] Financial Statements for the Research Council UK for year ended 31 March 2015.

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5.9.4 Benefit to Cost Ratios

The table below sets out estimates of the net benefits and costs of those elements of the programme funded by Innovate UK, combining the results described above (the wage premia for R&D workers have taken as the average of the range described). The results indicate that the estimated net benefits of the programme lay in a range of £1.1bn to £1.6bn, giving an overall range for the benefit to cost ratio (the £s of benefits per £1 of cost) of £3.03 to £6.63. The average of these results is £4.72 per £1 of cost.

Table 5.2: Estimated net benefits, BMC awards made by Innovate UK

	Valuations based on Pitchbook (Low)	Valuations based on Pitchbook (High)	Valuations based on survey results
Estimated impact on business values (£m)	1,509	1,766	1,140
Leakage	0.07	0.07	0.07
Estimated net impact on business values (£m)	1,403	1,643	1,060
Total net benefits of the programme (£m)	**1,403**	**1,643**	**1,060**
Costs (low estimate, £m)	248	248	248
Benefit to Cost Ratio, £ per £1 of cost, high estimate	**5.66**	**6.63**	**4.27**
Costs (high estimate, £m)	349.90	349.90	349.90
Benefit to Cost Ratio, £ per £1 of cost, low estimate	**4.01**	**4.70**	**3.03**

5.9.5 Other benefits

A focus on business values will only partially capture the benefits of the programme. It is anticipated that the programme may lead to several other benefits, including:

- Licensing outcomes: As noted elsewhere, licensing forms an important component of the exploitation plans of both businesses and academics applying for funding through the BMC. The income generated from these licenses – both in terms of fees paid to the businesses or academic institutions and potential profits arising from onward development exploitation by the licensee – would also ideally be considered within the analysis. However, it has not been possible to develop systematic evidence on these types of outcomes and the causal effects of the programme, as they are not tracked systematically through monitoring and there are no publicly available or proprietary datasets that could be used to identify these deals.

- Knowledge spill-overs: The programme may also result in wider benefits in terms of generating knowledge (such as improved understanding of fundamental disease biology) that could be built on or exploited by others. These effects could be mediated by the publication of findings resulting from preclinical studies or clinical trials, through formal or informal interactions between researchers, or via circulation of researchers in the labour market (e.g. where lead innovators move to new companies and apply the skills acquired in other contexts). Such impacts could be expected to be long term in nature. An analysis of the 14 patents reported by academics funded by the MRC (equivalent data is not available for businesses funded by Innovate UK), suggested that only one had been was cited by a subsequent patent. As such, the extent of these types of knowledge spill-overs – at least in terms of further product development – may be minimal at this stage, though clearly would be an area of interest for a long-term impact evaluation.

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- Demonstration effects: The programme has in part supported the development of novel technologies (e.g. cell and gene therapies) characterised by high levels of risk. To the degree that the research funded through the programme has helped demonstrate that these technologies are safe and effective, this may have de-risked investment in analogous technologies, stimulating the commitment of additional resources to R&D and product development. These potential effects are not considered in this evaluation, which focuses primarily on the direct impacts of the grants funded.

- Health benefits and savings to national health systems: The development of new health products has the potential to deliver other types of benefit, including improved care and quality of life for patients. There may also be scope for savings for national health systems through adopting the technologies emerging from the programme (although many novel therapies simultaneously produce increases in quality of life and costs for health systems, as highlighted in NICE's assessment of the Strimvelis therapy for Adenosine Deaminase Deficiency developed by GlaxoSmithKline[52]). The nature of health systems – characterised by monopsonies and budgetary constraints – may reinforce the point that the social returns to many projects could exceed the private returns.

Given the omissions described above (which are unknown in magnitude), the cost-benefit analysis should be viewed as a lower bound for the potential benefits arising from the programme.

[52] Strimvelis for treating adenosine deaminase deficiency-severe combined immunodeficiency, Evaluation Consultation Document, NICE, 2017

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6 Conclusions

This section sets out the conclusions from the evaluation.

6.1 Impact against objectives

Overall, the BMC has proven to be a successful programme in stimulating investment in the life science sectors and accelerating the development of the biomedical technologies. It has largely delivered against its two core objectives relating to impact:

- Deliver growth to the UK life sciences sector: The programme led to significant impacts in leveraging private investment into the UK life sciences sector and supporting the expansion of R&D programmes. These effects have arisen both from the awards made by Innovate UK to businesses and through the spin-outs supported by the Medical Research Council (though there was limited prevalence of impacts via licensing at this stage). The evidence suggests that these effects are likely to persist well beyond 2018.

- Deliver innovative life sciences products and services more quickly and more effectively into healthcare: There was a range of evidence that the development of technologies being developed by applicants to the programme had been accelerated by the funding made available. However, the duration of product development cycles in the biomedical sector is such there was little evidence of new technologies being commercialised, and most applicants expected a new product to be launched by 2025 or beyond. There was also evidence that the CiC programme is helping to strengthen the pipeline of innovative projects emerging from academic institutions, though there was less robust evidence that the Innovate UK awards for Feasibility Studies on their own de-risked technologies sufficiently attract private investment.

There was a variety of evidence to suggest that these outcomes can be directly attributed to the grant. This evidence was derived from comparisons between those awarded funding and comparison group of businesses that did not. The findings were subject to a range of robustness checks to provide a greater level of confidence that the findings were causal in nature. The findings were also largely consistent across a variety of independent datasets, helping to raise confidence in the findings.

6.2 Value for money

The results of the evaluation also suggest that the programme was an efficient instrument for achieving those objectives:

- Leverage: All components of the programme leveraged significant additional resources into translational research and R&D. Each £1 of funding made available to the CiC programme was matched by £1.46 of funding from private or charitable sources. Spin-outs established on the back of DPFS raised £8.16 of private capital for every £1 of DPFS funding awarded. The Innovate UK grants led to an additional £0.76 to £1.48 in private R&D spending per £1 of public sector spending by 2018 (and £3.99 to £5.09 in private capital). Comparisons with evaluations of other initiatives suggest the programme has been at minimum as effective as R&D tax credits in stimulating private R&D investment, and the findings broadly aligns with past research examining the impact of public and charitably funded medical research on private R&D spending[53]. However, these effects were at the margins of overall private R&D spending in the sector (which totalled £4.3bn in 2017).

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- Cost benefit analysis: A cost-benefit analysis of the grants awarded to businesses by Innovate UK related the benefits of the programme embodied in the increase in the value of businesses and wage premia accruing to R&D workers suggested that the BMC also offered strong value for money with a central estimate of the benefit to cost ratio (BCR) of £4.72 per £1 invested. This substantially exceeds the hurdle rate of return typically applied in the approval of the Business Cases for these types of scheme. It is more challenging to determine the rate of return on MRC's investments in translational research owing to the timeframes for the study, though the evidence suggests that the economic value of commercialisation outcomes achieved by 2018 substantially exceed the costs incurred in funding the CiC and DPFS programmes (a range of £1.72 to £16.39 per £1 committed for the DPFS).

While the marginal rate of return is unknown, this does raise questions as to whether the budget for the programme was sufficiently large to maximise the social returns from the programme. It should be noted these findings rest an assumption that markets efficiently price the values of the businesses concerned, and there may be merit in tracking their valuations over a longer time horizon to validate these results.

6.3 Wider issues

The evaluation raises some wider issues for possible consideration in the design of future programmes:

- Externalisation of exploitation: A high share of applicants plan to externalise the long-term exploitation of the technologies under development by selling the underlying intellectual property or reaching a licensing agreement with third parties. Given the high share of M&A activity led by overseas businesses, this highlights a risk that the long-term exploitation of the intellectual property takes place overseas. This risk is widely recognised, and the evidence from the evaluation does not suggest that the underlying issues have eased since the programme was launched. Clearly, there are few policy levers available to Innovate UK and the MRC that could help address this risk.

- Feasibility studies: The findings of the evaluation consistently did not provide robust evidence that the Feasibility Study awards had a significant impact on the outcomes of interest to the evaluation. These are smaller programmes of developmental funding designed to help industrial applicants find proof of concept for their ideas, and typically involve smaller amounts of funding. The evidence suggested that these studies did progress and provided valuable findings that sometimes led onto follow-on R&D. However, the evidence suggested that these projects did not systematically attract private finance to support their onward progression. This may indicate that funding for proof-of-concept studies alone does not provide sufficient de-risking of technologies to attract private investment and further public support for pre-clinical and early clinical research may be required to leverage sufficient interest from venture capitalists and other investors.

- Spatial issues: There was some evidence that businesses or PIs associated with institutions located in the UK's main venture capital hubs (London, Oxford and Cambridge) were more effective in leveraging private investment to support onward progression of the assets under development. This could be explained by the density of the relevant regional innovation systems, enabling businesses, academics and universities can make links with investors more straightforwardly than in other areas. However, these patterns may also be related to the properties of the underpinning science – the most successful businesses were involved in the development of advanced therapies, and efforts to develop these technologies have been concentrated in these hubs. This may have implications for the future targeting of funding, and complementary activity that could help maximise the returns on public sector spending (such as bridging activity to help those located in peripheral areas make stronger links to industry or investors).

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- Supply chains: There was evidence that some projects reach an early conclusion because the supply chain formed was insufficiently robust to changes in the external context (e.g. changes in the strategic direction of suppliers could make vital inputs unavailable, inhibiting the delivery of the study). While these risks are outside of the direct control of those taking funded projects forwards, there may be benefits in requiring applicants to consider the resilience of their project proposal to these types of 'worst-case' scenarios.

6.4 Further evaluation

The benefits of the Biomedical Catalyst have not been fully realised, and this study has focused on intermediate impacts. There may be merits in completing an evaluation of the programme considering its effects over ten or more years, to provide a more comprehensive understanding of the effects of this type of initiative over very long timescales. If there was interest in pursuing such a study, it would be beneficial to consider the following in developing a suitable methodology:

- Business performance data: This evaluation made use of the Business Structure Database to estimate the impact of the programme on the businesses receiving funding from Innovate UK. The turnover data captured in this data has lags owing to the way that the information is compiled, which could lead to understatement of the programme's effects. It is understood that BEIS have developed a longitudinal version of the Interdepartmental Business Register that makes use of more timely HMRC VAT and PAYE records that could be explored as an alternative.

- Tracking assets: In the longer term, the assets under development may be taken forward by other businesses where they are licensed or where the spin-outs or businesses receiving grants are bought out. A survey based approach to collecting the information needed will become less effective in these cases, and it will be important to make use of secondary data to chart the onward progress of the assets of interest. Data sources such as Pitchbook or Beauhurst will be helpful in tracking acquisitions, while the on-line databases of clinical trial records will aid an understanding of onward progression through the development pathway.

- Health benefits: In the very long term, it may be possible to determine the health benefits of any technologies that were successfully commercialised. Such information could be compiled from any published health economic analyses that formed part of late stage trials, or from Health Technology Assessments completed.

- Knowledge spill-overs: Finally, knowledge spill-overs are likely to become more significant in the longer-term. These should be investigated by examining citation patterns to knowledge based outputs (publications and patents). Details of patents have not been collected by Innovate UK through monitoring, so this may require extraction of the IP filings made by relevant businesses from databases such as PATSTAT.

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