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Biomedical Catalyst Evaluation

Process Evaluation and Baseline Impact Evaluation

Ipsos MORI
Biomedical Catalyst Evaluation:
Process Evaluation and Baseline Impact Evaluation
Preface

This report is a result of an independent evaluation of the Biomedical Catalyst undertaken by Ipsos MORI’s Policy and Evaluation Team, commissioned as a joint initiative by Innovate UK and the Medical Research Council (MRC) in November 2014. The evaluation has involved a triangulation of secondary evidence, and both qualitative and quantitative primary data collection. Nevertheless, there are references throughout the report which relate to views held by a small number of individuals from stakeholder or applicant groups, and where findings are of an indicative nature this is highlighted in the text. The authors are grateful for the support and cooperativeness of the staff involved in the policy and implementation functions of the programme and all those who contributed to the evaluation. The timing of this report is early within the lifetime of many of the projects supported by the Biomedical Catalyst, and many of their outcomes may be limited at this stage. The objective of this report is to serve as a baseline and an early analysis of impact. The results presented in this report also draw from a limited dataset covering the first six rounds of funding up to February 2015. Some results, particularly where they focus on an individual round of funding, or a subset of projects, may not be statistically significant, but could be indicative of early trends. Nevertheless the applied methodology was thorough and high response rates in the survey have resulted in the development of robust evidence.
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Summary

Ipsos MORI was commissioned in November 2014 to undertake a process and an impact evaluation of the Biomedical Catalyst. This report presents the objectives, the proposed approach and initial findings from the first phase of the study, incorporating findings from stakeholder interviews, case studies and an applicant survey.

Aims and Objectives of the Evaluation

The overall aim of the process evaluation, is to provide a comprehensive view of the following:

- The Innovate UK and Medical Research Council partnership and how it delivers the Biomedical Catalyst
- The appropriateness and robustness of the current processes and funding mechanisms and
- The current balance of the portfolio relative to the remit and scope of the programme.

In relation to the impact evaluation, Innovate UK and the Medical Research Council realise that many longer term impacts are unlikely to have occurred at this stage given the long development process of many of the technologies being funded. As such, this investigation focuses on setting out:

- A baseline for the assessment of impact
- The intermediate and final impacts which can be measured within the timeframe of this study, and the proposed approach for doing this and
- The intermediate and final impacts which may be realised beyond the timeframe of this study.

A further wave of fieldwork will be delivered in 2017 to more fully capture and evaluate the impact of the Biomedical Catalyst.

The Biomedical Catalyst

Established in 2012 as part of a wider package of measures to support the life sciences sector, the Biomedical Catalyst involves provision of £240m of funding to target three related objectives:

- 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 both academically and commercially led research and development in a seamless, effective and efficient manner.

Delivered in partnership between the Medical Research Council and Innovate UK the scheme offers funding to life sciences projects at varying stages of technical and commercial development: Confidence-In-Concept (CiC) awards for portfolios of small projects at the earliest stages of technical development by academic institutions, Feasibility awards (comparable in focus to the CiC awards, but awarded on a firm-by-firm basis by Innovate UK), and more substantial funding for pre-clinical and clinical work through the early and late-stage awards (funding is available up to a Phase II clinical trial or equivalent).
Strategic and economic rationale

Global markets for medical technology and biotechnology are projected to grow rapidly as a consequence of both an aging population and increasing per-capita health spending\(^1\). The UK has traditionally been competitive in the life sciences sector, and is supported by an internationally competitive academic infrastructure. This level of expertise would suggest that the UK is well placed to exploit the opportunities presented by global growth in healthcare expenditure. However, R&D investment in the sector peaked at £4.9bn in 2011 before falling to just £4.0bn in 2013 (in nominal terms)\(^2\). Two important factors have contributed to this disinvestment: the widely publicised ‘patent cliff’ in which expiry of patents on a large number of highly profitable drugs has eroded revenues, while the cost of R&D has increased, attributable in part to the rising cost of the clinical trials required for regulatory approval\(^3\) and the failure of many new drugs in trials\(^4\).

Disinvestment by large firms has been compensated by growth in small businesses, typically focused on a small number of targets and reliant on equity rather than profits to fund R&D activity (making it more challenging to secure the resources required, as described below). Additionally, a range of barriers to translating basic research discoveries into commercial products have been identified that may be partly responsible for declining R&D productivity, particularly the broad trajectory of increasing fragmentation of basic and clinical research since the 1970s. In order to exploit the commercial opportunities presented by growth in global demand for healthcare, a sufficient supply of finance to the growing number of smaller firms driving growth in the sector will be needed, as well as action to support the commercialisation or translation of knowledge generated within academic institutions.

The central market failure rationale justifying public investment in the Biomedical Catalyst relates to imperfections in capital markets that inhibit the flow of finance into the life sciences. Such imperfections are caused by information asymmetries by which the investee has greater knowledge of the scientific risks associated with the project than the investor. For equity investment, there are also moral hazard problems in which the investee has an incentive to pursue less risky commercial objectives after the finance is secured. Features of the life sciences sector exacerbate these issues: the costs and risks of failure of R&D are typically high, while the complex nature of the underlying science makes it challenging for non-specialists to appraise those risks without incurring substantial transaction costs to acquire the needed technical information. As such, subsidies for R&D expenditure have the potential to both address financial market constraints directly and ‘de-risk’ projects.

Other market failures may also be present. In particular, the possibility of effects by which the innovating firm cannot internalise the full benefits of their activities may also act to restrain investment in R&D at sub-optimal levels. Life sciences firms are particularly exposed to these risks as they typically publish the results of clinical trials as means of encouraging adoption by national health systems. Additionally, while patenting may offer protection, patent registrations are in the public domain, giving competitors insight into the compounds or devices being explored. This ability to free-ride on the investment made by competitors provides a supplementary economic rationale for the Biomedical Catalyst as subsidies will to some extent compensate for the inability of applicants to fully internalise the returns of R&D activity.

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\(^1\) Strength and Opportunity, The Landscape of the Medical Technology, Medical Biotechnology, and Industrial Biotechnology Sectors in the UK, HM Government, 2010

\(^2\) Business Enterprise Research and Development 2013, Office for National Statistics, November 2013

\(^3\) Stifling New Cures: The True Cost of Lengthy Clinical Trials, Avik Roy, Manhattan Institute for Policy Research, 2012

Theory of Change and Logic Model

The Biomedical Catalyst programme can be expected to achieve impact through the following steps:

- **Inputs:** This evaluation report was compiled using data from the first six rounds of Biomedical Catalyst funding. At the time of publication eight rounds had been completed. Further resources are absorbed in the delivery of the programme in terms of the MRC and Innovate UK secretariat administering the scheme and time contributed by independent assessors, peer reviewers and the Developmental Pathway Funding Scheme (DPFS) and Major Awards Committee (MAC) panel members in the assessment of project applications. Additionally, other organisations (such as the Knowledge Transfer Networks and industry associations) will have incurred costs in promoting the programme to their audiences. Applicants and potential applicants will also incur costs through the preparation of application forms, and in the use of their own resources where grant funding has been matched.

- **Activities:** Applicants to the Biomedical Catalyst are required to provide detailed project plans and an assessment of the commercial potential of the product under development. Following submission of the application, the project is subject to a detailed assessment and review process employed to give rigorous scrutiny to both the scientific and commercial case for the investment of public funds. These judgements are then employed to make final decisions on grant awards. Following the grant decision, the major activity supported by the Biomedical Catalyst is the provision of the agreed grant and the monitoring of the biomedical research and development activities led by academics or firms (or collaborations between the two) supported.

- **Outputs:** The primary outputs of the Biomedical Catalyst are associated with the delivery of the supported research and development projects and include: increases in R&D expenditure, direct and indirect increases in R&D employment and GVA as well as knowledge and research outputs.

- **Direct outcomes:** The programme is associated with the following outcomes: technological progress, the development of new intellectual property, leverage of additional investment into life sciences projects, improved commercial planning skills for academics, and greater levels of collaboration between academics and industry in the sector. Grant funding for projects can be expected to support progress towards a range of exit strategies including the formation of spin-out companies for academic intellectual property (IP), licencing or selling IP to firms, and progress towards commercial production and sale of a product or service. For unsuccessful applicants there is the potential for the Biomedical Catalyst to accelerate the rate at which a project closes or is forced to commercialise.

- **Indirect outcomes:** The following effects may also be observed beyond the population of successful grant applicants: broader changes in university behaviour towards a greater emphasis on translational research and commercialisation, spill-over effects as the new knowledge generated on projects leaks out beyond their organisations, as well as through demonstration effects.

- **Economic and social impacts:** It is anticipated that the outcomes outlined above would lead to increased sales, profits, GVA and employment as well as positive human health effects. This would be associated with a range of displacement, multiplier and leakage effects.

This discussion around the anticipated effects of the Biomedical Catalyst is summarised in the logic model presented below.
Process evaluation findings

The following top-line messages emerged from the course of the research:

- **Marketing and communication**: The evaluation showed that the programme has been well communicated and largely effective in raising awareness across the communities of interest. The Medical Research Council built on an existing programme and established communication channels. Innovate UK communicated with subsets of relevant sectors through a number of industry associations. There is an opportunity however to better develop the Biomedical Catalyst brand and highlight the two distinct routes for industry and academic-led projects, as well as to target some specific groups (med-tech companies and universities without medical schools).

- **Application**: Applicants found the process of applying and submitting the application forms relatively straightforward. It may help to improve the quality of the assessments from firms if the Innovate UK application form highlights the opportunity for applicants to include a scientific annex offering further detail.

- **Assessment**: The assessment processes are well set up by Innovate UK and the Medical Research Council but the limited pool of assessors of Innovate UK results in a perceived variability in the quality of the judgements made on applications. Feedback to applicants is seen as an important part of the process and both the Medical Research Council and Innovate UK make strong efforts to give constructive feedback to
applicants in both stages of the two stage process. Medical Research Council’s feedback is more detailed and is associated with higher levels of satisfaction.

- **Project selection**: Is performed by panels made up of highly regarded and experienced individuals from the fields of science, business, and venture capital, who are well placed to judge the scientific and commercial potential of the projects. Panels scrutinise details behind the science and proposed method and the study team is confident in their technical ability to select the applications with highest potential for the pull through of academic research. Supporting the growth of the sector by responding to market failures is considered to some extent, but this appears to be a less prominent factor in the decision making process. Concern was also expressed by a number of stakeholders that the panels’ expectations around applicants’ ability to have tested the science behind their ideas may have made the panel selection processes more risk averse than necessary. There may also be scope for Innovate UK to better help industry applicants to prepare for the panel.

- **Due diligence and monitoring**: Both organisations, the Medical Research Council and Innovate UK, use standard contracting, due diligence and monitoring processes. The focus of Innovate UK on project management and monitoring relates to the applicant’s self-written project plan. The Medical Research Council operates a milestone driven monitoring process in which the milestones are often set by the panel and have scientific outputs that form gateways to progress to the next project phase (such as substance particular test score for an assay). Each of the approaches has pros and cons. Aggregated performance management in the Medical Research Council is organised by regular meetings revisiting live projects on a red, amber green (RAG) rating of each specific milestone. Innovate UK’s approach is more pragmatic, also following quarterly monitoring meetings, but focusing on escalating any issues to the Lead Technologist as and when they arise. The differences between Medical Research Council and Innovate UK processes partly reflect differences in the organisations’ focus and their key audiences. There may be scope nevertheless to incorporate additional scrutiny of scientific progress into Innovate UK processes.

**Early evidence of impact**

As identified above, the long term impacts of the project will be increased sales, profits, GVA and employment as well as positive human health effects. However, the projects supported by the Biomedical Catalyst are long term in nature and in some cases have started very recently. It is too early to assess impact against these metrics. Instead a range of econometric techniques (propensity score matching, Ordinary Least Squares (OLS) and negative binomial regressions and a regression discontinuity design) have been used to explore an early assessment of the causal effects of the Biomedical catalyst on key outcomes of interest:

- **Project progress**: The results indicate that the programme has had a significant and substantial impact in the acceleration of the projects forming the focus of Biomedical Catalyst applications. The estimates suggest that (on average) to date the Biomedical Catalyst has caused these projects to progress almost one Technology Readiness Level® (TRL) stage further than they would have done otherwise.

- **Project spending**: The estimates suggest that the provision of funding has had a significant impact on investment in the projects forming the focus of the Biomedical Catalyst applications. The impact on spending grows in each year following the application, supporting the view that the lack of a ‘treatment effect’ in year two relates more strongly to the discrete nature of the TRL scale than a failure to progress further.

- **Applicant level impacts**: Results at the level of the applicant (either a firm or academic team) are more ambiguous. When looking at the findings at the level of the applicant, it was not possible to reject the

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5 Technology Readiness Levels (TRL) are a method of estimating technology maturity. TRL are based on a scale from 1 to 9 with 9 being the most mature technology. The use of TRLs enables consistent, uniform, discussions of technical maturity across different types of technology.
hypotheses that the Biomedical Catalyst has had no impact on total R&D spending or R&D employment. The results also seem to indicate that the Biomedical Catalyst has had a negative impact (overall) on the levels of external funding raised following the notification of the award (this excludes any funding contingent on a Biomedical Catalyst award). This can be largely explained by the Medical Research Council funding rules preventing ‘double-funding’ of the project (i.e. academic applicants are prevented from seeking additional finance for the funded project), and indeed this is confirmed by the results - the negative impacts are confined to the academic applicants, while no effect is observed amongst the firms.

These statistical results, together with the qualitative evidence gathered by the study team offer the following early assessment of the likely impact of the programme:

- **Progress:** The projects funded through the Biomedical Catalyst have shown progress since notification of the award, with the proportion at the clinical trials stage doubling from 14 to 28 per cent and similar progression observed from exploratory stages to in-vitro and in-vivo experiments (or equivalents). The progress made was also more rapid than that observed amongst unsuccessful applicants.

- **R&D activity relating to the project:** Successful applicants saw R&D expenditure relating to the project rise faster in absolute terms than unsuccessful applicants. However, R&D expenditure relating to the project rose faster in percentage terms amongst unsuccessful applicants. This is partly explained by the lower base from which unsuccessful applicants were starting.

- **Broader R&D activity:** Similar patterns were observed for total annual R&D expenditure, which rose at a slower rate than expenditure on the project forming the focus of the Biomedical Catalyst application. This suggests that both successful and unsuccessful applicants have undergone a process of diverting resources away from other areas to focus on these projects.

- **Funding:** Successful applicants had attracted higher levels of funding from private or public sources than unsuccessful applicants at the time of their application, and appear to have had greater success in securing additional funds following the award (though not necessarily in connection with the project).

- **Collaboration:** The survey did not provide substantial evidence to suggest that the Biomedical Catalyst has had a large effect on collaboration to date. Successful applicants to the fund were less likely than unsuccessful applicants to report that they engaged in collaborative relationships to deliver projects. Approximately half of both successful and unsuccessful applicants suggested that they had formed novel collaborative relationships (suggesting that funding may not have caused the formation of new relationships, though it is possible that this was an effect of the process of developing applications). There was, however, a suggestion that the new collaborative relationships formed by successful applicants were potentially more productive than those formed by their unsuccessful counterparts.

- **Research output:** Successful applicants were less likely to have produced research outputs (in the form of conference papers, presentations of results at conferences or events, or journal articles) to disseminate their research than unsuccessful applicants. This could be indicative of commercial secrecy an unwillingness to publish until patents have been registered, or could reflect that the delivery of the Biomedical Catalyst award is diverting attention away from these activities.

- **Turnover:** The turnover of successful firms rose more rapidly than that of unsuccessful applicants, though for the majority, annual sales were zero at both the time of the application and the survey. It is difficult to link this result to Biomedical Catalyst funding, as so few had brought a product to market, though there were indications that some applicants had been able to secure licensing agreements which may be contributing to the changes observed.

- **Employment:** Total employment rose more rapidly amongst successful applicants than unsuccessful applicants, though at a similar order of magnitude as R&D employment. This suggests that any jobs created to date are likely to be associated with the implementation of R&D projects rather than production, and it is not
anticipated that the Biomedical Catalyst will have had any wider effects on output (GVA) beyond the wages received by R&D staff, or productivity at this early stage (which aligns with prior expectations).

These gross outcomes are summarised in the table below:

Table 2 – Gross Outcomes: Total Change Between Time of Application and February 2015

<table>
<thead>
<tr>
<th></th>
<th>Successful Applicants</th>
<th>Unsuccessful Applicants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Application</td>
<td>Feb 15</td>
</tr>
<tr>
<td>Cumulative Project Expenditure (£m)</td>
<td>141.0</td>
<td>205.0</td>
</tr>
<tr>
<td>Annual R&amp;D expenditure (£m)</td>
<td>100.0</td>
<td>112.0</td>
</tr>
<tr>
<td>R&amp;D Employment</td>
<td>740</td>
<td>920</td>
</tr>
<tr>
<td>Overall Funding (£m)</td>
<td>292.0</td>
<td>484.0</td>
</tr>
<tr>
<td>Total employment</td>
<td>930</td>
<td>1,170</td>
</tr>
<tr>
<td>Total turnover (£m)</td>
<td>71.0</td>
<td>88.5</td>
</tr>
</tbody>
</table>

Source: Ipsos MORI (2015), based on unweighted figures

Conclusions and Recommendations

The process and impact findings above highlight the considerable strengths of the programme in particular around the effectiveness of marketing and communications activities, project selection, as well as in achieving technological progress and indications of positive additionality. The Biomedical Catalyst has also seen high levels of demand over the course of the first six rounds of the competition, and Innovate UK and the Medical Research Council have faced no major challenges in committing funding at the levels foreseen. There is little strong evidence to suggest that there has been a supply-side response in financial markets to this growth in demand in the UK, which implies a clear strategic requirement for the type of funding offered through the Biomedical Catalyst.

Evidence on how far the programme is delivering against its strategic objectives is summarised in the table below:

Table 3 – Progress against Programme Objectives

<table>
<thead>
<tr>
<th></th>
<th>Progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deliver growth to the UK life sciences sector</td>
<td>It has not been possible to establish a quantifiable net effect at the level of individual applicants to the programme (either whole firms or academic team). Given the timeframes involved in bringing new products to market in the life sciences sector, it is too early to judge how far the programme has supported the growth of the sector. However, there is some evidence from the process evaluation that in the future, resource allocation processes might be adjusted to strengthen focus on how far projects are likely to proceed without public investment to avoid any crowding out of private sector investment (an issue that may not have been problematic over the course of programme delivery, given the weak supply of capital to the sector over this period).</td>
</tr>
</tbody>
</table>
The evaluation has identified evidence that the Biomedical Catalyst is accelerating the development of the projects it supports. Project selection processes appear to be strong, and we can have confidence in their ability to select the projects with the highest potential for the pull through of academic research. Together, this suggests that the programme is helping to deliver innovative life sciences projects more quickly than would otherwise have been the case. There may however, be an opportunity for the programme to better support the most radical and innovative proposals where there remains a major uncertainty about the viability of the underpinning science.

The twin strands of the programme ensure that it is able to invest in research and development ideas emerging from both commercial and academic environments. It is able to support teams of either academic or commercial researchers and to support most combinations of the two groups. The design of the programme is also highly supportive of collaboration between academic and commercial groups. Alternative support arrangements are not seamless however, and there is an opportunity for the academic and commercial strands of the programme to better market what each other offers.

The research has also identified a number of opportunities to support the development of the Biomedical Catalyst. In considering the future development of the programme (or any successor programme) it may be helpful to consider the following:

- **Marketing and communications:** There is a need for the Medical Research Council and Innovate UK to collaborate to develop a comprehensive marketing strategy for any future rounds of the programme. The design of this will need to consider:

  - How best to market the scheme to the broader biomedical community including med-tech communities and the emerging area of digital health.
  - Opportunities to better develop and leverage the brand of the Biomedical Catalyst and highlight its rigorous approach to selecting the best translational R&D projects.
  - Notwithstanding a high number of participating universities, the programme could consider alternative channels to raise awareness about participating (mainly in a partner role) in the Biomedical Catalyst programme.

- **Application process:** It may help to improve the quality of the assessment of applications from firms if the guidance associated with the Innovate UK application form is strengthened to stress the importance of including a scientific annex offering further detail on any science which they consider to be new and innovative within their application. Additionally, guidance to applicants could include information on the probability of success of applications at the MAC and the possible topics for discussion.

- **Assessment process:** Corrective action is recommended regarding the independent assessment of applications to Innovate UK, which currently, in the Biomedical Catalyst specific context, does not add substantial value to the project selection process while causing unnecessary reputational issues for the programme. A number of possible options could be explored. The first would be to substantially strengthen the independent assessment process through expanding the current pool of registered assessors (though it is acknowledged that Innovate UK is making steps towards this goal) to improve the depth and breadth of expertise that can be applied (the Medical Research Council is in a position to assist with refinement of this process). It should be noted that stakeholder interviews highlighted that consulted assessors are highly
qualified and experienced scientists and entrepreneurs in relevant field. Changes in how Innovate UK assessors offer feedback, including a shift towards a more narrative style, and removing the expectation of all assessors to comment on applications from all perspectives could help to improve the perceived quality of feedback received. A possible solution to the variable quality in assessments would be to introduce an additional quality assurance by asking a trusted assessor to run a check on review outputs or give more time to panel members to consider the successful bids at the review stage. Due to the distrust of the assessment system which was evident amongst a range of stakeholders, it might be advisable to engage chairs of the MAC in briefing the assessors and or in the discussions surrounding borderline proposals (which may or may not make it to the MAC) – an issue explored further in the next section. However, a low cost alternative would be to remove the independent assessment of full-stage applications altogether (as few full-stage applications do not make it through the independent assessment process to the MAC).

- **Additionality**: Additional guidance could be provided to panel members to focus their attention more strongly and clearly on issues of commercial impact and additionality. This is likely to become increasingly important if financial conditions continue to improve.

- **Flexibility**: In cases where the MAC feel that the science behind a promising application has not been adequately tested there may be scope for the panel to recommend that the applicant receives a supplementary award with conditional milestones to conduct the key missing studies. Successful execution of the supplementary studies would unlock further funding; if unsuccessful, funds for subsequent studies would be recycled into later competition rounds. This approach would be appropriate in cases where the project is seen as particularly innovative, the commercial potential as strong and where there is a clear reason why the project could not secure funding through an alternative route.

- **Monitoring**: The differences between Medical Research Council and Innovate UK processes partly reflect differences in the organisations’ focus and their key audiences. Despite having a systematic approach, where the monitoring officers flag issues that they identify to the Lead Technologists who do have a high level of scientific knowledge, there may be scope to incorporate additional scrutiny of scientific progress into Innovate UK processes. This could be achieved through the pooling of expertise (such scientific monitoring will likely require specialist domain-relevant expertise that cannot necessarily be supplied by Innovate UK monitoring officers (MOs)). It should be noted that although in many cases MOs are experts in the relevant scientific area, under the current terms of the MO role they can ask questions about a project but must not give advice (this applies across all of Innovate UK programmes).

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6 The extent to which the Biomedical Catalyst supported effects that would not have arisen without the funding
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). This report presents the objectives, the proposed approach and initial findings from the first phase of the study, incorporating findings from stakeholder interviews, case studies and the applicant survey.

1.1 Evaluation Objectives

The evaluation of the Biomedical Catalyst comprises two key elements: an impact evaluation focusing on establishing the causal effects of the programme on the outcomes observed, and a process evaluation examining the effectiveness of the underlying delivery processes.

The overall aim of the process evaluation, as defined in the invitation to tender, is to provide a comprehensive view of the following:

- The Innovate UK/ Medical Research Council partnership and how it delivers the Biomedical Catalyst
- The appropriateness and robustness of the current processes and funding mechanisms and
- The current balance of the portfolio relative to the remit and scope of the programme.

In relation to the impact evaluation, Innovate UK and the Medical Research Council realise that many longer term impacts are unlikely to have occurred at this stage given the long development process of many of the technologies being funded. As such, the focus of this investigation is:

- A baseline for the assessment of impact
- The intermediate and final impacts which can be measured within the lifetime of the study, and the proposed approach for doing this and
- The intermediate and final impacts which may be realised beyond the lifetime of the study.

1.2 Methodology

This report is based on a range of tasks completed by the team over the course of the study described under a number of subheadings below:

1.2.1 Evaluation framework development

The study began with the development of an initial evaluation framework, comprising an overall theoretical framework for the impact and process evaluations, identification of the preferred options for the impact evaluation given data availability constraints, and a framework for completing an economic evaluation. This was developed on the basis of the following tasks:

- **Familiarisation:** Initially, the study team conducted 13 interviews with internal stakeholders, who were involved in the design and delivery of the programme to gain an understanding of the programme. This exercise covered key policy, appraisals, and contracting leads within the Medical Research Council and Innovate UK, as well as those involved in the independent awards committees (the Major Awards Committee and the Development Pathway Funding Scheme).
- **Document Review and logic model development**: Through a review of internal documents, the study team further refined its understanding of the underlying logic of intervention, market failures motivating intervention, and the potential economic and social benefits anticipated. These documents included policy and delivery descriptions, award criteria, competition documents, guidance to applicants and guidance to assessors.

- **Literature review**: Finally, a brief internal literature review was undertaken to support research options for the impact and economic evaluation studies.

- **Analysis of Application, Appraisal and Monitoring Information**: Analysis of the data was used to better understand the plausible use of impact evaluation options and to review the likely sample sizes that may be available for analysis, highlighting implications for the evaluation.

An extract from the evaluation framework is provided in Annex A.

### 1.2.2 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, data which was comprehensive and maps every eligible application (including outlines) according to modality and disease areas. Additionally, a review of publicly available data on the performance of the life sciences sector was completed to examine the strength of the rationale for the programme.

### 1.2.3 Stakeholder Consultation

Thirty one consultations, with internal and external stakeholders, were completed in order to support both the process and impact evaluation. There were two specific stakeholder topic guides (provided in Annex F): one for the investor community and one for all other internal and external stakeholders. The focus of the latter was two main areas: the effectiveness of the processes employed to deliver the Biomedical Catalyst, and views (and substantiating evidence) on how far the scheme had performed - with regards to delivering its policy objectives. The summary table below presents achieved interviews by consultation type:

<table>
<thead>
<tr>
<th>Stakeholder Sample</th>
<th>Number of consultations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Programme Secretariat and MOs</td>
<td>10</td>
</tr>
<tr>
<td>Assessors</td>
<td>2</td>
</tr>
<tr>
<td>CiC, DPFS, and MAC</td>
<td>4</td>
</tr>
<tr>
<td>Member organisations, Investment community and investors</td>
<td>11</td>
</tr>
<tr>
<td>Wider Policy</td>
<td>4</td>
</tr>
</tbody>
</table>

### 1.2.4 Survey

A census telephone survey was undertaken of all applicants submitting a full-stage application to the Biomedical Catalyst in rounds one to six who did not opt out of the survey. This includes all applicants to Innovate UK's

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7 Individuals who had historically opted out of receiving marketing communications from Innovate UK in general were given the chance to opt back into the survey
Feasibility Studies programme, and all applicants to the Early and Late Stage awards who were not declined at the outline bid or expression of interest stage. Applicants to the Medical Research Council Confidence-in-Concept (CIC) programme were not included in the survey (as the delegated nature of the funds lent themselves more to qualitative forms of exploration). The questionnaire for this survey is in Annex C. The survey period was extended by a week to obtain a higher response rate and a more representative sample of successful and unsuccessful applicants. As a result, the survey covered 207 applicants and achieved a response rate of 73 per cent.

1.2.5 Case Studies

A total of 20 case studies were undertaken covering 5 Confidence-in-Concept awards, 5 unsuccessful applications and 10 projects which were the subject of successful applications. The case study development involved triangulation of documentary evidence (application forms, appraisal data, and monitoring data) with in-depth qualitative research with the applicants concerned (including collaborators) and wider secondary evidence. For Confidence-in-Concept awards, the case studies involved initial discussions with the Research Office before drilling down into a sample of the individual projects funded. These initial discussions also examined the effects of Biomedical Catalyst funding on broader metrics of university behaviour around translational research and industry-academic collaboration. Case study topic guides and list of case studied projects are included in Annex D. Each case study covered issues relating to the strength of the scientific, commercial, and human health rationale for the project, funding issues, progress made, the wider effects of the project, and broader commercial exploitation plans, alongside an examination of process issues.

1.2.6 Data-linking

A data-linking exercise has been completing linking records of successful and unsuccessful applicants to sources of longitudinal secondary data. This includes the Business Structure Database and Business Expenditure on Research and Development survey (via the Office for National Statistics Virtual Microdata Laboratory), and computerised patent records available through the European Patent Office (PATSTAT). Owing to lags in the data, this evidence cannot be used to assess the effectiveness of the programme, but does provide a baseline for the programme which will be revisited in 2017 as part of the final evaluation (at which point it will be feasible to extend the analysis beyond lead applicants to the CMOs and CROs that have been involved in delivering projects funded through the Biomedical Catalyst). A short summary of the initial results is provided in Annex G.

1.3 Structure of this Report

The remainder of this report is structured as follows

- **Section 2 – Biomedical Catalyst Programme**: This sets out the descriptive understanding of the programme rationale and intervention logic drawing heavily on the evaluation framework, the expected outcomes, programme delivery processes and the process evaluation framework.
- **Section 3 – Strategic Rationale**: This section covers recent trends in the life sciences sector and how well the programme is aligned with the wider policy context.
- **Section 4 – Delivery**: This section describes in detail the progress achieved so far and presents the project portfolio of the programme, with project characteristics and indicative results from the survey.
- **Section 5 – Process Evaluation**: This section provides a detailed assessment of the effectiveness of the processes employed to deliver the Biomedical Catalyst.
- **Section 6 – Baseline and Early Evidence of Impact**: This section covers the emerging findings from the assessment of the outcomes achieved by the Biomedical Catalyst.
Section 7 – Conclusions and recommendations: This section sets out the main conclusions and recommendations from the study.

In addition, the following annexes are appended to the report:

- **Annex A: Impact Evaluation Framework** – a detailed outline of the impact evaluation framework defined at the outset of this evaluation, providing a theoretical framework for understanding the effects of the Biomedical Catalyst.
- **Annex B: Process Evaluation Framework** – a description of the processes employed to deliver the Biomedical Catalyst, and the elaboration of a set of questions to be addressed through the study.
- **Annex C: Survey** – a technical outline of the survey of applicants completed as part of this evaluation.
- **Annex D: Econometric Analysis** – details of the econometric analyses completed as part of this evaluation.
- **Annex E: Case studies** – summaries of the sixteen of the twenty case studies of successful and unsuccessful projects completed as part of this study (four of the applicants involved in case studies did not agree to publication).
- **Annex F: Research Instruments** – a compilation of all research instruments used in the evaluation.
- **Annex G: Data Linking** – a short summary of the results of the data-linking exercise.
2 Biomedical Catalyst

This section sets out an overview of the Biomedical Catalyst programme, its aims, objectives and its anticipated outcomes (serving as an overall framework for this evaluation). In addition, this section provides a description of the processes employed in the delivery of the scheme, their function in contributing to the overall aims and objectives of the programme and, again, a set of evaluation questions for assessing their effectiveness.

2.1 Biomedical Catalyst

The Biomedical Catalyst programme was created in 2012 as part of a wider package of measures to support the growth of the life sciences sector under the Industrial Strategy. The policy aims of the Biomedical Catalyst are to:

- Deliver growth to the UK life sciences sector
- Deliver innovative life sciences products and services quicker and more quickly into healthcare
- Provide support to both academically and commercially led research and development in a seamless, effective and efficient manner.

The Biomedical Catalyst involves £240m of grant funding for pre-clinical and clinical R&D projects and is delivered jointly by the Medical Research Council and Innovate UK. The scheme involves four distinct types of grant awards targeted at projects at different stages of technical and commercial development: Confidence-In-Concept awards for portfolios of small projects at the earliest stages of technical development by academic institutions, Feasibility awards (comparable in focus to the Confidence-In-Concept awards, but awarded on a firm-by-firm basis by Innovate UK), and more substantial funding for pre-clinical and clinical work through the early and late-stage awards (funding is available up to a Phase II clinical trial or equivalent).

2.1.1 Innovate UK

Innovate UK is the UK’s innovation agency with its main role being to support and connect innovative businesses to accelerate sustainable economic growth. Its key responsibilities are to:

- Provide new support for innovative small and medium-sized enterprises (SMEs) with high-growth potential
- Make sure that government initiatives such as the SBRI (Small Business Research Initiative) attract innovative UK businesses and give companies access to important customers in the public sector
- Identify and invest in the sectors that have the greatest potential for innovation to speed up economic growth
- Help innovative companies work with their backers so their ideas can be developed commercially

2.1.2 The Medical Research Council

The Medical Research Council is one of the UK’s research councils with its mission (set out in its Royal Charter) to:

- Encourage and support research to improve human health
- Produce skilled researchers
- Advance and disseminate knowledge and technology to improve the quality of life and the economic competitiveness of the UK

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8 Industrial strategy: government and industry in partnership, BIS, 2013
• Promote dialogue with the public about medical research

2.2 Programme Rationale and Intervention Logic

This section summarises the rationale for the programme of public support offered through the Biomedical Catalyst, and the causal process by which the programme is expected to deliver its objectives (and associated outputs, outcomes and impacts). A more comprehensive discussion is set out in Annex A.

2.2.1 Rationale

The rationale for public investment in the Biomedical Catalyst programme can be broadly split into two key elements: a strategic case relating to the scale of the economic opportunity presented by growth in the life sciences sector, and an economic case relating to the presence of market failures inhibiting investment in R&D.

Strategic case

Global markets for medical technology and biotechnology are projected to grow rapidly as a consequence of both an aging population and increasing per-capita health spending. The UK has traditionally been competitive in the life sciences sector that accounted for 8 per cent of UK manufacturing GVA, and 28 per cent of business R&D expenditure in 2011, and is supported by an internationally competitive academic infrastructure. This level of expertise would suggest that the UK is well placed to exploit the opportunities presented by global growth in healthcare expenditure. However, R&D investment in the sector peaked at £4.9bn in 2011 (after 30 years of almost uninterrupted growth) before falling to just £4.0bn in 2013 (albeit still accounting for over 22 per cent of total UK R&D investment). Two important factors have contributed to this disinvestment: the widely publicised ‘patent cliff’ in which expiry of patents on a large number of highly profitable drugs has eroded revenues, while the cost of R&D has increased, attributable in part to the rising cost of the clinical trials required for regulatory approval and the failure of many new drugs in trials.

Disinvestment by large firms been compensated by growth in small businesses, typically focused on a small number of targets, and reliant on equity rather than profits to fund R&D activity (making it more challenging to secure the resources required, as described below). Additionally, a range of barriers to translating basic research discoveries into commercial products have been identified in the literature (that may be partly responsible for declining R&D productivity). In particular, a broad trajectory of increasing fragmentation of basic and clinical research since the 1970s has been observed. This has led to falling knowledge of patient needs amongst basic researchers, and difficulties in processing the large volumes of increasingly complex findings amongst biomedical researchers (with the collaboration between the two often failing to emerge). In order to exploit the commercial opportunities presented by growth in global demand for healthcare, a sufficient supply of finance to the growing number of smaller firms driving growth in the sector will be needed, as well as action to support the commercialisation or translation of knowledge generated within academic institutions. Close collaborative working between academics and industry (or clinicians) is also needed to ensure that (1) industry-led R&D is based on a sound understanding of underlying science and research, and (2) the process of translation draws in sufficient understanding of both patient needs and the regulatory frameworks involved.

9 Strength and Opportunity, The Landscape of the Medical Technology, Medical Biotechnology, and Industrial Biotechnology Sectors in the UK, HM Government, 2010
10 Business Enterprise Research and Development 2013, Office for National Statistics, November 2013
**Economic Rationale**

The central market failure rationale justifying public investment in the Biomedical Catalyst relates to imperfections in the capital markets that inhibit the flow of finance into the life sciences sector to fund projects that would deliver a (risk-weighted) rate of return higher than the risk-free rate of return\(^\text{13}\). Such imperfections are caused by information asymmetries by which the investee has greater knowledge of the scientific risks associated with the project than the investor (allowing them to mask known deficiencies if present). In these circumstances, the investor is forced to approximate these types of risks involved on the basis of market-wide returns, or to incur costs in acquiring additional information through due diligence, offering funds at too high a cost for some potentially profitable projects. For equity investment, there are also moral hazard problems in which the investee has an incentive to pursue less risky commercial objectives after the finance is secured. These can be solved through the introduction of monitoring obligations (such as the venture capitalist taking a seat on the firm’s board), though the transaction costs involved may mean it is only efficient to make relatively large scale investments (inhibiting the supply of finance for smaller projects).

Features of the life sciences sector exacerbate these issues: the costs and risks of failure of R&D are typically high, while the highly complex nature of the underlying science will make it challenging for non-specialists to appraise those risks without incurring substantial transaction costs to acquire the needed technical information. This may not have been problematic for large pharmaceutical firms while profits remained high and they were able to fund R&D from profits, though the growing number of smaller firms (or academics seeking to commercialise innovation developed in academic institutions) will be more dependent on equity investment to fund the costs involved. As such, subsidies for R&D expenditure have the potential to both address financial market constraints directly and de-risk projects (though provision of equity or subsidies for the transaction costs involved could potentially achieve a similar result).

Other market failures may also be present. In particular, the possibility of effects by which the innovating firm cannot internalise the full benefits of their activities may also act to restrain investment in R&D at sub-optimal levels. Life sciences firms are particularly exposed to these risks as they typically publish the results of clinical trials as a means of encouraging adoption by national health systems. Additionally, while patenting may offer protection, patent registrations are in the public domain, giving competitors insight into the compounds or devices being explored (it is clear from applications to the BMC that applicants have a strong awareness of the potential competing products currently under development and their relative strengths). The ability to free-ride on the investment made by competitors provides a supplementary economic rationale for the Biomedical Catalyst (as subsidies will, to some extent, compensate for the inability of applicants to fully internalise the returns of R&D activity).

### 2.2.2 Theory of Change and Logic Model

This section articulates the expected causal process by which the Biomedical Catalyst programme will deliver its intended results. While this framework largely defines the range of outcomes and uncertainties that will need to be explored through the impact evaluation, a number of issues are highlighted that will also require attention through the process evaluation.

**Inputs**

The Biomedical Catalyst involves £240m of grant funding for research and development activities, representing the primary resource input into the programme. However, a range of further resources are absorbed in its delivery, largely in the form of the staffing inputs provided by Innovate UK and Medical Research Council.
programme secretariat in the administration and monitoring of the scheme, and the time contributed by independent assessors, peer reviewers and the DPFS and MAC panel members, in the assessment of project applications. Additionally, other organisations (such as the Knowledge Transfer Networks and industry associations) will have incurred costs in promoting the programme to their audiences. Applicants and potential applicants will also incur costs through the preparation of application forms, as well as costs in the form of their own resources where grant funding has been matched.

Activities
The Biomedical Catalyst comprises a number of activities (the process aspects of which are given more detailed consideration below):

- **Application and project selection process**: Applicants to the Biomedical Catalyst are required to provide detailed project plans and an assessment of the commercial potential of the product under development. Following submission of the application, the project is subject to a detailed assessment and review process employed to give rigorous scrutiny to both the scientific and commercial case for investment of public funds. These judgements are then employed to make final decisions on grant awards.

- **Subsidies for research and development**: The major activity supported by the Biomedical Catalyst is the provision and monitoring of research and development subsidies for translation and research and development projects in the biomedical sector led by academics or firms (or collaborations between the two).

Outputs
The primary outputs of the Biomedical Catalyst will be those associated with the delivery of the research and development projects receiving funding through the scheme:

- **Increases in R&D expenditure**: The assumed economic rationale for the Biomedical Catalyst is that there are market failures (largely information asymmetries) in capital markets inhibiting the flow of finance into translation and other R&D projects in the life sciences sector. If the scheme is effective in meeting its objectives, it is anticipated that a key output would be an increase in research and development expenditure amongst successful firms. To achieve these aims, the programme needs to be targeted at infra-marginal projects (i.e. those that would not have been taken forward using alternative sources of funding such as private finance or public grant programmes), implying project selection processes require due consideration of additionality (the extent to which the projects would not have moved forwards without public sector funding). R&D expenditure may not rise in aggregate if subsidies cause diversion of investment or time away from alternative research activities.

- **Direct and indirect increases in R&D employment and GVA**: The increase in R&D expenditure will lead to increases in R&D employment and output (in the form of wages for R&D workers). These effects could be observed directly (i.e. within the applicant organisations themselves or among collaborators) or amongst any suppliers engaged to provide services. For both therapeutics and medical device projects, the applicant will often subcontract the delivery of clinical trials to a contract research organisation (CRO), the manufacture or synthesis of the clinical products under investigation to a contract manufacturing organisation (CMO), or other elements such as specific pieces of analysis or consultancy advice or regulatory advice.

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14 GVA is a measure of the economic output or value added through production (and is equal to the sum of wages and profits or to the value of sales less expenditures on finished goods and services).

15 Any additional demand for the services of the CMOs, CROs and other suppliers will place pressure on their capacity. If the additional demand cannot be accommodated within existing capacity, firms may either raise prices, or recruit additional workers (leading to price growth through pressure on earnings). As such, pressure on prices may dampen demand for these services elsewhere in the economy (unless investment is made in capacity).
• **Knowledge and research outputs:** The delivery of Biomedical Catalyst will lead to the generation of new knowledge, which may find broader dissemination in the form of publications in academic journals (or other research outputs, such as conference papers or presentation of results at events). While academics may have wider incentives to publish the results of their research, the publication of the results of clinical trials and similar also acts to encourage the adoption or consumption of any new products developed (as national health systems will typically require evidence that the treatments involved are both effective and cost-effective).

**Direct Outcomes**

A range of direct outcomes (i.e. on the projects forming the focus of Biomedical Catalyst applications, or the applicant organisations) might be anticipated as a consequence of the Biomedical Catalyst:

• **Technological progress:** A key aim of the Biomedical Catalyst is to accelerate the commercialisation of new products originating either in academia or the private sector (and over the timescale of the evaluation, will provide a fundamental measure of the overall success of the programme). Provided that funding is reaching infra-marginal projects with a sufficiently strong scientific rationale, then the funding should produce an effect in terms of bringing the products concerned closer or more quickly to market. Such an effect may endure beyond the duration for which subsidies are available.

• **Intellectual property:** Alongside technological progress, if the projects lead to knowledge that can be exploited commercially, then a patenting effect might also be anticipated. Level of patenting will also depend on baseline levels of technical development: for Late Stage awards, it is not anticipated that applicants will register new intellectual property, though such effects might plausibly be observed for projects at earlier stages of technical development.

• **Leverage:** As a consequence of the high cost of Phase III clinical trials, it is anticipated that applicants will need to raise substantial additional investment from the public (e.g. the National Institute for Health Research) or the private sector in order to progress projects once their project is complete. The Biomedical Catalyst has the potential to have a substantial effect on the ability of applicants to secure this finance through de-risking the projects involved, either as a result of the progress achieved through the project or information asymmetries being reduced as a consequence of the assessment of the scientific and commercial merits of each application through the project selection process. Restrictions on how far successful academic applicants are allowed to secure additional finance for their funded research activities from other sources may mean that any such effects may be delayed in these cases.

• **Commercial planning skills:** While it is anticipated that the application process will be in many respects familiar to the SMEs applying for R&D subsidies, there may be effects on applicants from academia. In particular, it was expected the application process would have the potential to help improve skills relating to the commercial planning of translation research projects, encouraging closer links with industrial partners, increasing the commercial potential of the research and making it more likely that the project is successfully brought to market through a variety of mechanisms (particularly if the applicant responds positively to the feedback received).

• **Collaboration:** The Biomedical Catalyst was created with a specific aspiration to stimulate greater levels of collaboration between academia and industry in the life sciences sector (with the wider aim of achieving greater pull-through of academic research into the commercial sector). Such collaborative effects could be catalysed in a number of ways: the process of preparing an application may foster collaboration through highlighting the need for academics to secure industrial partners (or vice versa), the publicity associated with Biomedical Catalyst may act to generate interest in collaborative working between academics and industry through raising wider awareness, while technical progress achieved through Biomedical Catalyst projects may also help secure the commitment and investment of industrial partners. In turn, this collaboration could bring
important direct improvements to the quality or commercial potential of the project, as well as more indirect effects through mutual learning or skills exchange.

- **Exit strategies:** The review of project application forms highlighted a number of exit strategies which may potentially be pursued by applicants with distinct implications for the character of the outcomes that might be observed. Academic or firm-led projects may choose to create a separate commercial entity to exploit the intellectual property generated, license or sell the intellectual property to other firms, or implement a business model based on the full-scale commercial production and sale of the product.

- **Unsuccessful applicants:** Given the hypothesised nature of the market failures justifying the project, failure to secure funding through the programme may have a substantial effect on unsuccessful applicants (at least, for those for whom the project was marginal). They may struggle to raise finance privately, and for those projects at a later stage of development where intellectual property has already been protected, delays will begin to erode the commercial potential of the project. As such, it would appear likely that many unsuccessful applicants would be forced to close (potentially ending development of the technology concerned). For academic-led projects, there is also the possibility that the research team is forced to commercialise before it is ready (which could lead to sub-optimal on-going development of the project in the absence of academic funds).

**Indirect Outcomes**

A number of effects might also be observed beyond the population of successful grant applicants:

- **Broader changes in university behaviour:** The scheme may leverage changes in behaviour amongst universities. For example, it may give the confidence that the availability of funding for translation research would justify investment in internal teams focused on identifying and developing proposals or research areas which have the potential for clinical application and later commercial exploitation. However, this would also be accompanied by the potential hazard that encouraging applications from those without the necessary skills to develop a translation research project of the highest quality would lead to wasted resources.

- **Spill-over effects:** Spill-over effects by which the knowledge developed through the project can be exploited by others are also possible, and are made more likely by the tendency of both firms and academics to publish the outcomes of R&D projects to secure acceptance from the public or from national health systems. This will allow other firms or researchers to free-ride on those investments by building on those results.

- **Demonstration effects:** The scheme also has the potential to deliver supplementary benefits through demonstration effects (‘de-risking’ innovative or novel research and development projects). As an example, for wholly new types of treatment (such as cell therapy) that have never reached regulatory approval, commercial investment may be constrained by the substantial risks and uncertainties involved. If the projects subsidised through the Biomedical Catalyst are able to reach regulatory approval for novel products, this may act as a signal to the market that further investment in these areas may generate commercial returns (in turn, improving the supply of finance for SMEs or spin-out activity). If more resource is directed at these areas (i.e., a crowding-in effect), a range of effects could be observed, such as increased levels of publications, patenting activity, and regulatory approval for additional new products.

**Economic and Social Impacts**

The outcomes outlined above are anticipated to lead on to the following economic and social impacts:

- **Sales, profit, GVA and employment:** Following regulatory approval and any post-marketing activities, initial economic impacts might be expected to be observed in the form of product sales or licensing fees, the profits associated with those sales, and increased employment (with the increase in total GVA produced represented by the sum of total additional profits and wages). In this case, direct employment impacts may be expected to
be modest: a review of longer-term business plans provided in Innovate UK application forms indicates that manufacturing of new products (both therapies and medical devices) is often expected to be undertaken by an external manufacturer on a contract basis. While applicants expect to create new jobs, these tend to be jobs associated with marketing or logistics rather than manufacturing.

- **Displacement**: The introduction of new medical therapies, devices, and diagnostic tools has the potential to lead to displacement effects in the product market. Where there are existing technologies available for treatment or diagnosis within the disease area of interest, sale of the new products is likely to cause a reduction in the sales (and associated employment and profits) amongst competitors. These effects will offset the economic impacts described above to the extent that the profits and wages associated with the production of the products displaced would otherwise have accrued to residents of the UK. As regulatory approval or adoption by national health systems will often require that the product is more effective than treatments which are already available, it can be anticipated that any displacement effects will be accompanied by an improvement in social welfare through human health effects or reductions in the cost of providing healthcare (in effect, an improvement in productivity).

- **Multiplier effects**: As highlighted above, the manufacture of the medical products developed through the programme will typically be undertaken by CMOs, and if the Biomedical Catalyst leads to the creation of new (or protection of existing) manufacturing jobs is will likely to be observed amongst CMOs rather than the applicants themselves (though the possibility that the applicant firm is acquired by a large pharmaceutical firm with its own manufacturing facilities cannot be ruled out). Equally, the potential for licensing agreements may mean that jobs associated with marketing and logistics arise in other firms. The extent to which these multiplier effects lead to employment and GVA effects within the UK will depend on the geographical distribution of the relevant CMOs.

- **Leakage**: It will be important to capture the scope of any effects by which the main economic benefits of the programme 'leak' away from the UK to foreign investors (and to some extent, such leakage effects might be anticipated on the basis of the current or future geographical profile of commercial investors in supported projects or firms). Those entering licensing agreements with applicants would also be expected to earn a profit on product sales (and again, it will be important to track the international distribution of such organisations to determine how far such profits are accruing to individuals resident in the UK).

- **Human health**: The main social benefit associated with the scheme will be the impacts on human health resulting from the introduction of new products, enabling diseases to be treated or diagnosed more cost-effectively. This will create benefits for patients (through enhanced quality of life) and for national health systems (through efficiency gains), potentially on a global basis. While the bulk of these effects will not accrue until products have been brought to market, there is a possibility that those patients involved in clinical trials will derive a health benefit from their participation.

**Logic Model**
The preceding discussion around the anticipated effects of the Biomedical Catalyst are summarised in the logic model presented overleaf.
2.3 Expected Outcomes

Proposed indicators for the key outcomes identified above are summarised in the table below broken down by relevance to commercial applicants or academic institutions. However, there are long timescales involved in bringing biomedical products to market (as explained in more detail in Annex A), particularly in the case of therapeutics, where the large scale clinical trials required to secure marketing approval can absorb significant time and cost. For example, one study has estimated the time required from the beginning of clinical testing through to marketing approval as 7 or 8 years\(^\text{16}\). It is possible to bring medical devices to market more rapidly, though timescales can be equally long where the device poses significant risks to human health (for example, those devices designed to sustain or prolong human life, or those designed to be implanted into the human body). Given these timescales, it is not anticipated that this evaluation (which is due to conclude in 2017/18) will be able to observe the full economic impacts and social benefits of the Biomedical Catalyst (though an ex-ante projection may be possible).

\(^{16}\) The Answer is 17 Years, What is the Question: Understanding Time Lags in Translational Research, Zoe Morris, Steve Wooding, and Jonathan Grant, Journal of the Royal Society of Medicine, 2013.
### Table 2.1 – Key Outcomes

<table>
<thead>
<tr>
<th>R&amp;D activity and leverage</th>
<th>Commercial Entities</th>
<th>Academic Institutions / Researchers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>R&amp;D expenditure</td>
<td>Resources invested in translation research projects</td>
</tr>
<tr>
<td></td>
<td>Private equity investment (cumulative)</td>
<td>Wider resource investment in translation research by HEIs (e.g. staff dedicated to identifying translation opportunities)</td>
</tr>
<tr>
<td></td>
<td>Propensity for IPOs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Capital raised through IPOs</td>
<td></td>
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<tr>
<td></td>
<td>Current market capitalisation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Investor confidence in life sciences</td>
<td></td>
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<tr>
<td></td>
<td>Supply of private finance to life sciences sector</td>
<td></td>
</tr>
<tr>
<td>Early Employment/ GVA</td>
<td>Employment and GVA amongst grant recipients</td>
<td>Number of researchers working on translation research projects</td>
</tr>
<tr>
<td></td>
<td>Employment and GVA of CROs and CMOs</td>
<td>Employment and GVA of CROs and CMOs</td>
</tr>
<tr>
<td>Collaboration</td>
<td>Number of academic partners</td>
<td>Number of industrial partners</td>
</tr>
<tr>
<td></td>
<td>Joint publications / patenting (proxy)</td>
<td>Joint publications / patenting (proxy)</td>
</tr>
<tr>
<td>Technical Progress</td>
<td>Technology Readiness Levels (TRL)</td>
<td>Technology Readiness Levels (TRL)</td>
</tr>
<tr>
<td></td>
<td>Regulatory approval</td>
<td>Regulatory approval</td>
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<tr>
<td></td>
<td>Propensity to progress to next TRL stage</td>
<td>Propensity to progress to next TRL stage</td>
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<tr>
<td></td>
<td>Propensity to submit follow-on application</td>
<td>Propensity to submit follow-on application</td>
</tr>
<tr>
<td>Patenting</td>
<td>Number of patents registered (by type)</td>
<td>Number of patents registered (by type)</td>
</tr>
<tr>
<td>Publications</td>
<td>Publication volumes</td>
<td>Publication volumes</td>
</tr>
<tr>
<td></td>
<td>Nature of publications</td>
<td>Nature of publications</td>
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<tr>
<td></td>
<td>Impact factor of journal publications</td>
<td>Impact factor of journal publications</td>
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<tr>
<td>Exit Strategies</td>
<td>Propensity to spin-out</td>
<td>Propensity to spin-out</td>
</tr>
<tr>
<td></td>
<td>Number of licensing agreements</td>
<td>Number of licensing agreements</td>
</tr>
<tr>
<td>Economic impacts</td>
<td>Sales</td>
<td>Sales</td>
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<tr>
<td></td>
<td>Profits</td>
<td>Profits</td>
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<tr>
<td></td>
<td>Employment</td>
<td>Employment</td>
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<tr>
<td></td>
<td>GVA</td>
<td>GVA</td>
</tr>
<tr>
<td></td>
<td>Productivity (Total Factor Productivity (TFP) / GVA per worker)</td>
<td>Productivity (TFP / GVA per worker)</td>
</tr>
<tr>
<td></td>
<td>Displacement in product markets</td>
<td>Displacement in product markets</td>
</tr>
<tr>
<td>Human Health</td>
<td>Quality Adjusted Life Years (QALY) gained</td>
<td>QALYs gained</td>
</tr>
<tr>
<td>Spill-over / crowding in</td>
<td>Patent citations</td>
<td>Patent citations</td>
</tr>
<tr>
<td></td>
<td>Publication citations</td>
<td>Publication citations</td>
</tr>
</tbody>
</table>

### 2.4 Programme Delivery Processes

The Biomedical Catalyst programme is delivered jointly by the Medical Research Council and Innovate UK. The former administers grants for translation projects led by academic institutions, while the latter administers grants for R&D projects originating from SMEs. Funding for the programmes originates from two separate Directorates of the Department for Business, Innovation and Skills (the Science and Innovation directorates respectively) and is not pooled for the purposes of the delivery of the programme (i.e. the Medical Research Council and Innovate UK are accountable for separate budgets).
In broad terms, the programme is delivered as a funding competition (which will have involved eight rounds by the end of 2014/15) in which academics and SMEs submit applications for grant funding to the Medical Research Council or Innovate UK respectively. Processes to allocate resources are broadly similar across the two organisations. Applications are appraised by external experts, with Early and Late Stage applications given detailed consideration by a project selection panel (the DPFS panel or the Major Awards Committee (MAC)). Only one process is formally shared across the two organisations: the MAC, which makes recommendations for funding decisions with respect to the Early and Late Stage strands of the Innovate UK programme and scores applications for ‘Late Stage’ awards to the Medical Research Council (i.e. those closest to commercialisation). Most other elements of the programme, whilst not shared, are well aligned.

2.4.1 Programme Secretariat and Competition Set-up

Both Innovate UK and the Medical Research Council maintain a programme secretariat responsible for the design and co-ordination of funding competitions, of which two to three have been delivered each year. Funding for each round is based on projections for the necessary spend required as dictated by the (annual) budget allocation and take into account any over or underspend from earlier rounds (in each round, funds will be committed to individual projects over a number of years, though individual projects may spend those funds more or less rapidly than originally anticipated). As the MAC is a shared process across Innovate UK and the Medical Research Council, and panel sessions can last up to three days, dates for these sessions are agreed between the two organisations well in advance.

2.4.2 Marketing

Both Innovate UK and the Medical Research Council undertake a range of marketing activity both as part of the specific funding round and on an on-going basis, to promote the Biomedical Catalyst programme. The primary objective of these processes is to secure a pool of high-quality applications from which to make funding decisions. However, as highlighted in the preceding section, there is a secondary goal to produce effects on the funding landscape (through raising awareness and confidence amongst the investment community). The primary vehicles for promoting the programme include:

- **Websites and webinars**: Both Innovate UK and Medical Research Council have created websites (or more precisely, areas of their own websites) to promote the programme and offer guidance to applicants.

- **Knowledge Transfer Network**: Innovate UK’s primary network for supporting business and thematic communities, KTN has provided a key role in promoting the Innovate UK element of the Biomedical Catalyst. Established to foster better collaboration between science, creativity and business, KTN has an outreach to 60,000+ SMEs, large business and academics. Communications are targeted through direct mail, monthly newsletters, events (including targeted Biomedical Catalyst meetings on digital health and medical devices) and one-to-one guidance to potential applicants.

- **Medical Research Council publicity activities**: The Medical Research Council primarily publicises calls for applications to the Biomedical Catalyst through university research offices (which then disseminate to individual academics). The Medical Research Council also undertakes outreach activities, visiting universities to raise awareness of the range of funding opportunities and offering guidance on priorities where appropriate.

- **Leverage of industry bodies**: Additionally, Innovate UK and the Medical Research Council have also exploited the presence of industry bodies representing the life sciences sector to promote the programme on a broader basis (e.g. the UK Bioindustry Association, BioNow and MediLink).

- **Other events**: Innovate UK and the Medical Research Council have organised or participated in a small number of events for the investor community to raise awareness. This is the main process by which the Biomedical Catalyst is expected to produce its anticipated wider effects on the funding landscape.
2.4.3 Application Process

Each funding competition involves an application process in which the applicant describes (broadly speaking) the project proposal, and the scientific, commercial, and management cases for funding (in varying levels of detail, depending on the type of funding being sought). The primary objective of the application process is to provide the Medical Research Council and Innovate UK (and other individuals involved in the project review and selection process) with sufficient information to assess alignment with programme goals and the strength of the scientific and commercial cases for investment.

The application process and nature of awards differs depending on the aspect of the Biomedical Catalyst being applied to, as set out in the table below.

Table 2.2 – Application Types

<table>
<thead>
<tr>
<th>Medical Research Council</th>
<th>Innovate UK</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Confidence-in-Concept (CIC):</strong></td>
<td><strong>Feasibility Studies:</strong> Focus of this category is the exploration and evaluation of the commercial potential of a scientific idea. Projects can be up to 12 months in duration, applying for a maximum grant of £200k. The grant may be up to a maximum of 70 per cent of the total project costs. The application process involves a single stage.</td>
</tr>
<tr>
<td>These awards are an additional development for the Medical Research Council in terms of their funding options. The awards are a form of devolved activity managed by universities. Each bid outlines how funding will be used, but does not have to detail the specific projects that will be supported. The university has discretion as to which projects receive funding over the grant period. These are annual awards, offering between £250,000 and £1.2m.</td>
<td></td>
</tr>
<tr>
<td><strong>Early and Late Stage:</strong></td>
<td><strong>Early and Late Stage</strong> - Funding is available to support further development, testing, and evaluation of life sciences products and services, including pre-clinical studies and early phase clinical trials. Projects can be up to 3 years in length and up to £2.4m of grant funding is available. Applicants first submit an EOI, and if successful, are invited to submit a full application for funding. The funding and project durations are identical across Early and Late Stage grants, as is the application process.</td>
</tr>
<tr>
<td>Funding is available to support further development, testing, and evaluation of life sciences products and services, including pre-clinical studies and early phase clinical trials. Applicants prepare an outline application and, if successful, are invited to submit a full application for funding (within 8 months). The Medical Research Council determines which applications might be considered closest to market and most appropriate for late-stage award (i.e. review by the MAC).</td>
<td></td>
</tr>
</tbody>
</table>

2.4.4 Assessment and Peer Review

Most applications (including outline applications or EOIs) to the Biomedical Catalyst are assessed (or reviewed) by external experts with a view to providing an independent judgement on the scientific, commercial, and managerial merits of the applications received to the programme. However, there are differences both in the way in which these external experts are selected and in the way they assess the proposals submitted:

- **Innovate UK:** Each bid is reviewed by up to 5 industry experts, academics, or consultants with expertise in the scientific area of the application. These assessors are selected from a database of external experts recruited via previous experience of their competitions and general recruitment activity. Applications are scored from 1 to 10 across 10 criteria (generating a score from 10 to 100) alongside a narrative response to support each judgement made. Written guidance is provided to assessors to guide their assessment. Assessors also provide summary judgements on whether the project is in scope and whether it should be recommended for funding (or to proceed to the next stage). Scores are averaged across the five assessments to give an overall score for the application, resulting in a ranked list.
• **Medical Research Council:** Applications to the Early/Late Stage are assessed at outline stage by the Development Pathway Funding Scheme panel, which is formed of experts from across academia, industry and the investment community. At full stage the Medical Research Council identifies internationally renowned experts from across academia and industry with the specific scientific expertise needed to assess every element of the studies proposed in the applications received (with the aim of securing between three and five academic or industry experts to review each bid dependent on the duration of the grant). The peer review process leads primarily to narrative comments on the merits of the applications, though applications are also scored to provide a measure of quality.

• **Confidence-in-Concept awards:** Applications to CiC are scored by an independent panel of experts (the CiC panel) with scores categorised in terms of those that are of 'high,' 'medium' and 'low' priority.

2.4.5 Feasibility Studies and Confidence-in-Concept awards

Awards for Feasibility Studies and CiC are made solely on the basis of the ranked scores given by the independent assessors or the CiC panel respectively. For Innovate UK, the minimum scoring threshold (the line draw) is set at a score of 70 points in advance of the scoring process, and adjusted following scoring to account for the level of funding available and to ensure that there is at least a clear one point difference between the lowest scoring successful applicant and the next highest scoring applicant. Adjustments to scores may also occur if the Lead Technologist decides assessments are likely to be unreliable (for example, due to misunderstanding of the science), and they will be deleted from the overall marks. For the Medical Research Council, funding for Confidence-in-Concept awards is given to all ‘high’ priority applications, while all ‘low’ priority applications are declined. The CiC panel then reaches a consensus view on which ‘medium’ priority applications should receive funding. Funding is rationed across successful applicants to align with funds available.

2.4.6 Outline Bids and Expressions of Interest (EOIs)

The decision on whether to progress an outline bid (Early, or Late Stage) to a full-stage application is close to identical to the process adopted to judge Feasibility Studies and Confidence-in-Concept awards. However, in the case of the Medical Research Council arm of the programme, the decision is taken at the DPFS panel (which has a larger membership than the CiC panel). Feedback is provided to applicants on their outline bids or applications following notification of success (or not).

2.4.7 Project Selection (Early, and Late Stage)

Full applications to the Biomedical Catalyst are also scored or reviewed using the approach specified in section 2.4.4 before being considered by a formal project selection panel (the DPFS panel or the MAC). At this stage, the Medical Research Council determines whether a particular bid is sufficiently close to commercialisation to merit consideration by the MAC, with the underlying rationale being that the MAC provides a greater level of commercial expertise. Innovate UK, following the scoring of Early and Late Stage bids, undertakes a further ‘line-draw’ to limit the number of proposals considered by the MAC. The two panels operate in a similar manner:

• **Major Awards Committee:** The purpose of the MAC is to fully assess the viability of projects, using a wide range of criteria, and to prioritise for funding those that have the best chance of ultimately delivering impact. The MAC is composed of 8-12 academic, clinical, industry and life sciences investment experts, covering the full range of translational disciplines, and reviews applications over two or three days. For each application at least three of its members will be selected by the MAC secretariat to lead interviews of the applicants; members are selected for their knowledge of the technology or disease area. Applicants have to present their bid to the panel and then take questions. After each presentation, MAC members discuss the application again, before each member gives an anonymous score of between 1 and 10.
• **DPFS panel:** The DPFS panel serves an equivalent function to the MAC on the MRC arm of the programme, reviewing the earlier-stage academic-led applications. The procedure is similar to MAC, other than there is no interview with the applicant. Three or four designated panel members present the application to the overall panel for discussion, as with the MAC panel, applications are then ranked through anonymous scoring, using an electronic voting system. The ranking given is then used to make a selection for funding based on the available budget.

The MAC and the DPFS members use the same scoring criteria to guide their judgements. The guidance provides a framework setting the anticipated features of projects that would receive different scores. The guidance is organised under the themes of quality (focused on scientific quality), impact (focused on the scale of potential health or commercial effects) and productivity (return on investment for the UK, leverage, probability of successful delivery, and additional). Members of the panels each give a single score taking into these factors into account. An average score of 7 or above is considered fundable. Funding decisions (see below) take into account the score and the associated comments and commentary provided by the panel.

2.4.8 **Funder's Panel / Sign-off**

The final application stage for Innovate UK is a meeting of the Funder's Panel. This process is to ratify the recommendation made by the MAC, as it is an independent expert selection process. In addition to the final confirmation of the award, subject to financial checks being made, the Funder's Panel assembles representatives of Innovate UK’s operations team and allows them to review the new projects and provide formal sign-off against the relevant budget. This also allows other departments (e.g. monitoring or communications) to co-ordinate and plan future resource requirements, activity and marketing where relevant. For the Medical Research Council, sign-off on decisions is informed by discussions between the programme secretariat and panel chairs.

2.4.9 **Contracting and Due Diligence**

Innovate UK performs due diligence checks prior to a full grant offer letter being signed. These checks are completed by the internal project finance team (rather than externally at a cost to the applicant). As part of this process any issues relating to the financial plans or structure of projects are raised, and if action needs to be taken this will form part of the conditional offer letter sent to successful projects (which sets out the terms of the project agreement, and details any action points for the project team as part of due diligence).

All successful applicants for Medical Research Council funding will have to finalise an award agreement which is based on the milestones set out in their application. The key information that is detailed within the agreement is: the primary investigator receiving funding; the costs involved in the project; the timetable agreed; and the deliverables – in the form of outputs and/or exploitation plans. If a lead academic institution applies in collaboration with an industry partner, an additional Medical Research Council Industry Collaboration Agreement (MICA) is needed (summarising the contribution the industrial partner will be making to the project – either cash or in kind – and detailing the proposed arrangements for intellectual property assignment or licencing).

2.4.10 **Project Monitoring**

Innovate UK and the Medical Research Council use different approaches to monitor the progress of projects:

• **Innovate UK:** Monitoring is organised around tracking financial progress (on a quarterly basis) alongside a narrative assessment of progress to project delivery milestones structured around work packages (which are set out in the final grant offer letter). There is no formal requirement for quantitative monitoring of project outputs, though on project completion, applicants are requested to complete a survey to capture the project
outcomes. There is no post-project monitoring (i.e. beyond the lifetime of the project). Projects are assigned to a monitoring officer, who reports to a monitoring liaison officer, who then reports on a set of projects to the Lead Technologist.

- **Medical Research Council**: The Medical Research Council adopts a similar approach to tracking project progress (though financial progress is monitored on an on-going rather than a quarterly basis). However, the project delivery milestones also incorporate validation of the scientific results (i.e. facilitating monitoring of how far projects are progressing in technical terms), and there is formal quantitative monitoring of the achievement of these milestones. Project outputs are monitored through ResearchFish, an on-line tool which allows grant applicants to detail project results (such as new collaborations, acquisition of further funding, publications, patents, licensing, spin-outs, policy impacts, and a range of other measures). This monitoring extends for three years beyond the lifetime of the award (and is a mandatory requirement of the grant). Monitoring is led by monitoring officers within the Medical Research Council, who may take advice from the DPFS and MAC panel as appropriate.

Monitoring of project progress may result in contract variations (for example, if projects are being postponed). For Innovate UK, variations in delivery timescales have to be agreed by the Lead Technologist and require ‘good reasons for these changes’ (e.g. subcontractor failing to deliver a substance in time). Increases in project expenditure are not allowed and shifting project budget from one partner to the other requires Lead Technologist sign-off while changes to project scope can be agreed by the Lead Technologists. For the Medical Research Council, there is also a focus on the delivery of scientific results, and projects may be terminated if the project fails to achieve the criteria for onward progression put forward by the applicant at their proposal stage.

### 2.5 Process Evaluation Framework

This section sets out a range of process evaluation questions which have been addressed in this evaluation, building on the broad areas identified in the invitation to tender.

<table>
<thead>
<tr>
<th>Process Evaluation Questions</th>
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</thead>
<tbody>
<tr>
<td><strong>Marketing and Communications</strong></td>
</tr>
<tr>
<td>- How effective were marketing and communications in raising awareness of the Biomedical</td>
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<tr>
<td>Catalyst amongst the target audiences (including across different technology areas)?</td>
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<tr>
<td>- Did marketing and communications make the objectives of the Biomedical Catalyst,</td>
</tr>
<tr>
<td>eligibility criteria, and application process clear to applicants?</td>
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<tr>
<td>- Did marketing and communications materials make it clear how the bids would be appraised</td>
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<tr>
<td>and assessed?</td>
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<tr>
<td>- How effectively has the Biomedical Catalyst engaged the investment community in terms of</td>
</tr>
<tr>
<td>(1) raising awareness of the programme, (2) raising confidence in the processes employed</td>
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<tr>
<td>to administer the programme, (3) raising the profile of life sciences more generally as</td>
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<tr>
<td>potentially profitable sector for investment?</td>
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<tr>
<td><strong>Application Process</strong></td>
</tr>
<tr>
<td>- Was the process of completing an application for Biomedical Catalyst funding straightforward?</td>
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<tr>
<td>- How helpful were the guidance materials and one-to-one support provided by the Medical</td>
</tr>
<tr>
<td>Research Council and Innovate UK in helping applicants to understand what was required?</td>
</tr>
<tr>
<td>- Was the scale of transaction costs incurred by applicants in the preparation of applications proportionate? What level of opportunity costs was incurred by unsuccessful applicants?</td>
</tr>
<tr>
<td>- Did the application process provide sufficient information to enable a high-quality appraisal of bids?</td>
</tr>
<tr>
<td>- Did the process of completing an application lead to any benefits for the applicant (such as encouraging links with industrial partners)?</td>
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</tbody>
</table>
### Process Evaluation Questions

| Assessment or Review Process | To what extent are the criteria for making funding decisions sufficiently aligned with the overall policy objectives of the Biomedical Catalyst?  
|  | How far do individuals involved in the appraisal process have sufficient scientific and commercial expertise to provide a rigorous assessment of applications received?  
|  | To what extent does the guidance provided to appraisers provide a clear direction on the nature of the judgments to be made and a consistent measure of project quality across applications?  
|  | How far do considerations of additionality through the assessment or review process (i.e. whether the project would be funded without the BMC) influence project selection outcomes in a way that optimises value for money?  
|  | How far are the resources invested in assessment and review proportionate?  
|  | How far did feedback given to applicants as a result of the assessment and review process lead to material improvements in project design and/or the avoidance of wasted resources invested in application preparation? |
| Project Selection Process | Are the terms of reference for project selection panels aligned with the overall policy goals of the Biomedical Catalyst?  
|  | Do wider performance management regimes (including the need to defray resources) influence project selection priorities in any way?  
|  | Did project selection panels (CIC, DPFS and MAC) receive sufficient information from the assessment and review processes to make informed project selection recommendations?  
|  | Are panel members given a sufficient amount of time to consider each application in sufficient depth? |
| Contracting and Due Diligence | Are the timescales between application and contract award appropriate and do they have any impacts on the commercial viability of projects?  
|  | Did the specification of conditional/grant offer/award letters make the deliverables and monitoring requirements on successful applicants clear (to both applicants and monitoring officers)?  
|  | (Innovate UK only) Is the due diligence process sufficiently rigorous to avoid resources being lost through committing resources to businesses facing financial difficulties? |
| Delivery and Monitoring | Does project monitoring provide an adequate framework for understanding the progress of projects towards their objective and enable early identification of any possible issues?  
|  | Are the costs incurred by grant recipients, in complying with monitoring requirements, proportionate?  
|  | Are processes for agreeing variations in contracts proportionate and effective?  
|  | How effectively does information on the performance of successful applicants feed directly back into the appraisal process for future rounds? |
| Aggregate Performance Management | Do monitoring systems support effective performance management, risk management, and decision making?  
|  | How does aggregate performance management information feed back into the delivery of the programme (if at all)? |
| Partnership working | Do Innovate UK and the Medical Research Council have sufficiently effective processes in place on an operational level to align the delivery of funding competitions?  
|  | Does the level of partnership working between the two organisations serve to maximise the impact of the Biomedical Catalyst and the likelihood it will achieve its policy aims? |
3 Strategic Rationale

This section provides an assessment of the strength of the strategic rationale for the Biomedical Catalyst, drawing on an analysis of publicly available statistics on the performance of the life sciences sector, an analysis of the broader policy context, and integrating findings from the consultations with stakeholders and applicants completed as part of the study.

3.1 Recent trends in the Biomedical Sector

3.1.1 GVA in the Life Sciences Industry

In 2013 (the most recent year for which data is available), total output (GVA) in the life sciences sector\(^{17}\) was in the order of £8.7bn. The industry accounted for 2.5 per cent of total economic output produced in the UK (excluding financial intermediation). However, while the life sciences sector performed relatively well during the financial crisis of 2007/08 and its immediate aftermath, overall output has contracted (in nominal terms) in each year between 2011 and 2013 (as illustrated in the figure below). This broadly matches trends in biosciences internationally, though a recent report\(^{18}\) on the global biotechnology industry suggests that some recovery (in revenues) was achieved by publicly listed firms between 2012 and 2013.

Figure 3.1 – Annual growth in nominal GVA, Life Sciences sector and whole economy (excluding financial intermediation), 2008 to 2013

Source: Annual Business Survey, Office for National Statistics

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\(^{17}\) Classified as SIC21: Manufacturing of Pharmaceuticals and Pharmaceutical Preparations, SIC26.6: Manufacturing of Irradiation, Electromedical, and Electrotherapeutic Equipment, SIC32.5: Manufacture of Medical and Dental Instruments, and SIC72.11 Research and Development on Biotechnology. The Standard Industrial Classification is the framework used by the Office for National Statistics to classify industrial activity, while this definition of the life sciences sector was that adopted by the Office for Life Sciences in the preparation of the Life Sciences Competitiveness Indicators.

\(^{18}\) Beyond Borders, Unlocking Value, Ernst and Young, 2014
3.1.2 R&D spending

The decline in output has partly been driven by disinvestment in research and development by businesses. As illustrated in the figure below, R&D spending in the pharmaceutical sector grew faster than the UK economy between 1999 and 2011 (from £2.3bn to about £5.0bn, over 30 per cent of the UK total). However, R&D spending contracted substantially in the period 2011 to 2013 (with annual R&D spending falling by £800m over the period). Again, this broadly correlates with international experiences, though amongst publicly traded biotechnology firms, R&D spending began to recover in 2013 (a trend not visible in the UK).

Figure 3.2 – Change in R&D spending, 1999 to 2013, Pharmaceuticals and UK

The observed reduction in R&D spend is mainly driven by disinvestment by large pharmaceutical firms. Pfizer shut its site in Sandwich and moved about 100 staff to Cambridge; 1,500 GSK jobs were lost in Harlow; Merck lost 500 jobs from its Harlow site; Novartis lost about 1,000 jobs in East Sussex and moved to the US; AstraZeneca has also closed offices and has been consolidating sites. One of the primary causes of this disinvestment is the well-publicised ‘patent cliff’ where the sector was facing substantial losses of revenues on products on which the IP protection had expired, that were not being replaced by new product launches. As illustrated in the figure overleaf, the impact of IP expiry was expected to peak in 2012: the global pharmaceutical industry was anticipated to lose $38bn in revenues to IP expiry while the ratio of sales on new products launched to sales lost was expected to fall to unity. Part of this challenge has been driven by issues associated with falling R&D productivity (as described in the preceding section), though it was expected that the industry would begin to recover from these issues from 2013 onwards.

Source: Business Expenditure on Research and Development Survey, Office for National Statistics

19 It is not feasible to provide R&D spending in relation to medical devices, as such spending is grouped with the R&D activities focused on other precision instruments, including optical instruments and photographic equipment.
Figure 3.3 – Sales lost to IP Expired Products, and Ratio of Sales Replaced to Sales Lost to IP Expiry

Source: Beyond the Patent Cliff: Signs of Recovery in Biopharma, Accenture 2012

3.1.3 Industry Structure

The industry (as defined by the Standard Industrial Classification) can broadly be broken down into the following constituent sub-sectors:

- **Pharmaceuticals**: The pharmaceutical industry accounts for the majority (just under 75 per cent) of economic output in the life sciences industry, employs 50,000 workers, and is highly productive (with GVA per worker in excess of £128,000 in 2013). The number of small, medium and large businesses active in the sector remained stable over the period 2010 to 2014, though the number of micro-businesses grew by 25 per cent (to 380) over the period.

- **Medical devices**: Manufacturers of medical devices (combining manufacturing of irradiation, electromedical, electrotherapeutic equipment, and medical and dental instruments) accounts for a further 25 per cent of GVA produced by the life sciences industry, employing 39,000 workers. Productivity in the sector is less than half of that observed in the pharmaceuticals sector (at £54,000 of GVA per worker). The sector is composed of 1,500 micro-businesses, 500 SMEs, and a small number of large firms, and this general structure remained stable between 2010 and 2014.

- **Biotechnology**: The R&D on Biotechnology sub-sector produces little in the way of economic output (accounting for 2 to 3 per cent of total output, and turnover per firm was around 12 per cent of the average across the life sciences industry in 2013). This may be caused partly by the fact that projects become part of ‘pharmaceuticals’ once acquired/out-licensed (thus capping economic output within the biotechnology sub-sector). The biotechnology sub-sector is almost entirely composed of micro-businesses, the number of which grew rapidly (by 150 per cent) between 2010 and 2014.

These changes are broadly indicative of the fact that the disinvestment by large pharmaceutical firms has to some extent been accompanied by substantial growth in small R&D intensive firms. These firms typically have little in...
the way of existing revenue streams, and will, in the main, need to fund their R&D activities from external sources of funding (in the form of equity investment or from public spending).

Figure 3.4 – Growth in Number of Active Enterprises, Life Sciences, 2010 – 2014 (2010 = 100)

Source: Business Demography Statistics, Office for National Statistics

3.1.4 Supply of Private Capital

As noted above, small firms will typically rely on the supply of equity and private capital to fund their activities. The figure below provides British Venture Capital Association figures on venture capital supply over the period 2005 to 2013, and illustrates that the supply of private capital to the pharmaceutical and biotechnology sector in particular was low relative to the size and productivity of the industry (with venture capital tending to reach the healthcare equipment sector – analogous to medical devices – in larger volumes over the duration of the period). The data suggests that conditions improved (in general terms) from 2010 onwards, and the average deal size in the 2013 was in the order of £3.75m (suggesting that venture capital is being focused at the later pre-clinical and early clinical stages of the R&D process).

This picture fits with the evidence emerging from stakeholder interviews. 2011 was described as a very difficult year for the biotech industry. There was a strong sense from stakeholders that the availability of capital had almost completely dried-up (reflected in the figure overleaf). It was suggested that the situation was particularly constrained in the UK because in the run up to the credit crisis other European governments had started to invest heavily in their biomedical sectors, which seemed to be were catching up in terms of investor appeal. There was a consensus among stakeholders, however, that the supply of capital into the sector has been improving much more strongly than the statistics below would suggest. While it was noted that investment conditions had not returned to what were seen as ‘bubble’ levels in 2002, the current market was described as healthy by several stakeholders. It was suggested that this recovery had gathered pace in 2014, perhaps explaining why it is not identifiable within the venture capital funding data below (where 2013 is the latest year reported).
While the study team understand that the scheme was mooted before the downturn as a response to a broad range of market failures,\textsuperscript{20} a large proportion of stakeholders felt that an overriding rationale for the Biomedical Catalyst was the limited availability of funding in 2011. For several of these stakeholders, the improvement of the funding landscape was so strong that they suggested that this should be reflected in a change in the focus of the Biomedical Catalyst programme. This group felt that while investment had returned, the appetite for risk was lower amongst investors than it had been in the past. They suggested that this was a large enough shift to necessitate change to focus the Biomedical Catalyst towards earlier and more risky applications.

Several stakeholders also drew a distinction between the supply of capital for biotechnology and medical technology projects. It was suggested that the availability of funding for biotech projects was increasing much more rapidly than for medical technology. However, it appears to be difficult to disentangle issues relating to the supply and demand for capital for this group as many medical technology projects were described as ‘un-investable’. Similarly, two individuals interviewed by the study team did suggest that an apparent shortage of supply of capital might in practice relate to a demand issue and a particular reluctance of UK owners to release sufficient equity from their firms. It was suggested that this was often a major barrier holding back the growth of small biotechnology firms.

\textbf{Figure 3.5 – Venture Capital, Pharmaceuticals, Healthcare Equipment, and UK Total}

Source: British Venture Capital Association, Office for National Statistics

\subsection*{3.1.5 Labour Market}

In terms of the labour market, the sector has performed largely in line with UK trends. Employment in the industry remained comparatively static between 2008 and 2013 (if not on a downward trajectory), which in light of the overall job losses described in section 3.1.2 suggests that the growth in micro-businesses may also be having a compensatory effect on employment levels. The gross weekly earnings of biological scientists and biochemists

\textsuperscript{20} These are detailed in section 2.
have risen a little more rapidly than for all occupational groups as a whole (though 2013 saw a reduction in gross weekly pay).

Figure 3.6 – Employment and Earnings, Pharmaceutical Sector and UK

Source: Annual Business Survey and Annual Survey of Hours and Earnings, Office for National Statistics

3.2 Alignment with the Broader Funding Landscape and Policy Context

The Biomedical Catalyst appears to be well aligned with the broader policy context of support for the life sciences sector. The Catalyst is a central strand of the 2011 Life Sciences Strategy which was referred to at its launch and policy stakeholders noted that the Biomedical Catalyst represents its central and most significant policy intervention in this area. One year on, the report on the Life Sciences Strategy identified a number of complementary funding measures which have been set up with the strategy (and by extension the Biomedical Catalyst) in mind: the UK Research Partnership Investment Fund, the Regional Growth Fund, additional funding for dementia research and the Biobank.

The model of funding for the Biomedical Catalyst also appears to be complementary to a range of other public interventions. The MRC and other Research Councils support academic research into furthering understanding of health and disease and the subsequent development of novel technologies and approaches. Collectively this underpins and de-risks much of the work conducted in, and subsequently developed by, the commercial sector. A range of other Innovate UK-funded programmes focused on the commercial sector such as: Catapult Centres in the area of Cell Therapy, and Diagnostics for Stratified Medicine (now the Precision Medicine Catapult), can be seen to complement the Catalyst. These focus directly on pursuing projects and creating a physical home for new collaborations rather than the financial support model of the Catalyst. Similarly, a range of policy interventions have been established to support a number of digital healthcare projects such as the £23m DALLAS initiative and the Assisted Living Innovation Platform. Together these activities potentially provide a pipeline of innovation projects which can be developed to secure the more significant funding available from the Catalyst. Several stakeholders suggested that the higher levels of individual project funding available from the Biomedical Catalyst than other sources ensure that its awards do not duplicate or compete with these other schemes.
It also appears that the broader policy drive to support translational research aligns well with the objectives of the Biomedical Catalyst. A number of schemes and policy changes are encouraging a focus on translational research including the 2014 Research Excellence Framework and its assessment of the impact of the research delivered by academic departments. Capital funding for academic institutions has also changed to be increasingly supportive of university-industry collaboration. The Research Partnerships Investment Fund, for example exclusively supports collaborations between academic and non-academic groups, now represents a significant share of the science capital budget. The role of Local Enterprise Partnerships (LEPs) with respect to European Structural and Investment Funds has been strengthened. In comparison to previous rounds, universities will need to work more closely with business representatives on LEPs to access the €1bn of funding allocated for innovation via EU funds. Together these changes could be seen as changing the incentive structures facing medical schools and academic departments more generally to encourage a greater emphasis on translational research activities which have the potential to deliver health, economic or social benefits.

Stakeholders interviewed as part of this research identified a broader suite of policy changes which are making the UK an increasingly supportive environment for businesses in the life sciences sector. Together with the level of public funding on offer from the Biomedical Catalyst, these were identified as ‘making investors look at the UK again’:

- Sustained public support for excellent scientific research – a science budget which has been maintained in cash terms despite significant fiscal pressures
- An increasingly attractive tax environment for innovation: lower corporation taxes on profits, the Patent Box, increasingly generous R&D tax credits, and a number of tax breaks for entrepreneurs including the Seed Enterprise Investment Scheme SEIS, and Entrepreneurs’ Relief
- Success in sustaining a generally positive economic environment – rule of law, ease of patenting.

However, there is some risk of duplication between the Biomedical Catalyst and other public and third sector sources of funding. Many of the applicants interviewed by the study team, especially those with an academic background, felt that their projects were suitable to receive funding from a range of sources and would have been prepared to submit multiple applications for those projects (to both public and charity funded schemes) had they not been successful with the Biomedical Catalyst (though they also identified a range of specific strengths of the Biomedical Catalyst). This implies that in the mind of applicants there is an overlap between schemes. Despite the applicants’ perceived overlap, the diagram overleaf highlights the unique scope of the programme within the funding landscape.
Figure 3.7 – Healthcare Translational Research Funding

Healthcare Translational Research Funding

<table>
<thead>
<tr>
<th>Basic research</th>
<th>Prototype discovery &amp; design</th>
<th>Pre-clinical Development</th>
<th>Early clinical trials</th>
<th>Late clinical trials</th>
<th>Healthcare Delivery</th>
</tr>
</thead>
</table>

Biomedical Catalyst
(MRC/Innovate UK)

Research Councils (MRC, BBSRC, EPSRC etc.) & Charities

Red = Response mode funding open to SMEs as well as academics
Grey = Respond funding only open to academics
* = Academic only/Commissioned elements open to SMEs
** = Convertible loans & pathfinder grants (~£100k) for SMEs

Note: The diagram shows the position of the Biomedical Catalyst (BMC) as a response mode academic/SME funding scheme capable of supporting development of healthcare products from concept to near-commercialisation. No other equivalent sources of public or charity funding are able to support projects from across the healthcare spectrum, irrespective of disease or approach at this phase of development. Though, examples of charity funding are given in the diagram these are generally not open to applications from SMEs and none except the Wellcome Trust and CRUK have the resources to consistently support clinical trials of new therapeutics or diagnostics and so are largely unable to bridge a key step in the route to healthcare and commercial impact. Additionally, certain charity and public funding, for example CRUK, elements of Wellcome Trust funding, and the National Institute for Health Research, is dilutive or comes with a requirement for IP to reside in the public domain and so is less attractive and potentially less tractable to downstream commercialisation. Note that challenge-led sources of funding such as IMI (European Commission), Horizon 2020 (European Commission), or SBRI (Innovate UK) are not shown in the diagram as they represent focused sources of funding seeking to address a particular question or need.
The market opportunity for digital health has been identified by a number of commentators. This has translated into a very strong policy priority picked up by Innovate UK (and the NHS). However, stakeholders interviewed as part of the evaluation stressed that the organisations which may move into this digital health market are currently highly dispersed and, despite the scale of the market opportunity being very significant, many propositions were not seen as ready for investment. The Biomedical Catalyst has been designed to overcome a funding market failure, rather than the more complex co-ordination issues associated with the emergence of a new or radically different innovation ecosystem or public procurement challenges facing the advance of digital health. As discussed in section 5, there may be scope to better market the programme to this group of firms, but a radical programme redesign would be needed to fully align the Biomedical Catalyst with this policy priority. There may be other approaches, such as an Innovation Platform, that cater better to the needs of such a group.

### 3.3 Summary

- **Changing industrial structure**: Analysis of publicly available statistics confirms the general picture set out in the previous section: the life sciences sector has contracted since 2011, accompanied by disinvestment in R&D spending. This disinvestment has been driven to large extent by consolidation by large pharmaceutical firms that were facing substantial loss of revenues due to expiry of patents that were not being replaced by sales on new product launches. At the same time, there has been a substantial growth in micro-businesses, particularly within the pharmaceuticals and biotechnology sector that are likely to be highly R&D intensive.

- **Supply of capital**: The growth in small businesses is likely to lead to substantial growth in demand for private or public funding as these firms have little in the way of revenues from which to fund their activities. The supply of venture capital funding has not matched the growth in the number of small businesses, suggesting that the progress of R&D projects may be being inhibited by the types of financial market imperfections described in the previous chapter (supporting the rationale for the Biomedical Catalyst). However, there have been some suggestions that there may be issues on the demand side, where small firms are reluctant to accept equity investment owing to the dilution of their capital (these are challenges that could not be addressed with such a programme). Additionally, there is anecdotal evidence that conditions have recently improved in the sector, with the supply of venture capital rising substantially in 2014 (though this goes beyond the data it has been feasible to gather as part of this study), though focused primarily on lower risk and later stage projects. As such, there may be merit in considering the shape of any future programme of this nature (though the absence of objective data may make it difficult to be precise).

- **Alignment with the broader policy context**: Overall it appears that the Biomedical Catalyst is well aligned with the policy context established by the 2010-2015 coalition government. Looking to the future, there may be opportunities to improve this fit by consideration of the relationship with a broad range of health research funding, as well as adapting to the priorities of the new government.

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4 Delivery

This section provides an analysis of the progress made in the delivery of the Biomedical Catalyst to date, in terms of committing funding to projects, the defrayment of grant expenditure, and the delivery of outputs. This section draws primarily on an analysis of the management information collected through the application, project selection, monitoring processes adopted by Innovate UK and the Medical Research Council in the delivery of the programme.

4.1 Applications Received

4.1.1 Total Applications Received

A total of seven competition rounds were completed by the end of March 2015, though the analysis in following sub-sections is based on the data available for the first six rounds (as the seventh round was completed only during the preparation of this report). The management information suggested that a total of 1,182 outline bids and EOIs were received over the course of the first six rounds along with 652 full applications for funding (including for Feasibility Studies and Confidence-in-Concept awards). The full-stage applications involved a total request for grant funding of some £800m, £600m in excess of the £200m funding available for these rounds.

Table 4.1 – Number and Value of Applications Received

<table>
<thead>
<tr>
<th></th>
<th>Number of EOIs and Outline Bids</th>
<th>Number of Full-stage Applications</th>
<th>Number of funded projects</th>
<th>Total Grant Funding Requested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confidence-in-Concept</td>
<td>-</td>
<td>62</td>
<td>36</td>
<td>£40m</td>
</tr>
<tr>
<td>Medical Research Council Early/Late Stage</td>
<td>387</td>
<td>173</td>
<td>56</td>
<td>£252m</td>
</tr>
<tr>
<td>Innovate UK</td>
<td>795</td>
<td>417</td>
<td>163</td>
<td>£511m</td>
</tr>
<tr>
<td>Total</td>
<td>1,182</td>
<td>652</td>
<td>255</td>
<td>£803m</td>
</tr>
</tbody>
</table>

Source: Monitoring Information from Innovate UK and the Medical Research Council

4.1.2 Applications by Product Type

There is no comprehensive categorisation of all the applications received by the Biomedical Catalyst programme, though applications received by the Medical Research Council are classified by modality (and disease area) according to standardised, accepted criteria. Additionally, the survey of successful and unsuccessful applicants aimed to collect similar data across both academic and firm led bids. In combination, the data suggested that the applications received by the programme are broadly representative of the composition of the biomedical industry as a whole as described in the preceding section. The majority of applications received related to the development of new drugs, with around 10 to 20 per cent relating to the development of medical devices. This

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23 Innovate UK bids are classified by product type in application forms, but this information is not compiled in a separate database.

24 http://www.hrcsonline.net/
broadly reflects the relative volume of output, although, not the numbers of enterprises across the different subsectors (although it is not known how far these patterns reflect broader levels of R&D spending, as the publicly available statistics are not broken in this level of detail).

Table 4.2 – Applications by Product Type

<table>
<thead>
<tr>
<th>Medical Research Council monitoring information (All outline applications)</th>
<th>Percentage</th>
<th>Survey Findings (Full-stage Applications)</th>
<th>Percentage of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs</td>
<td>45</td>
<td>Therapeutics</td>
<td>54</td>
</tr>
<tr>
<td>Cellular and Gene Therapy</td>
<td>9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaccine</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preventative Intervention</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Devices</td>
<td>9</td>
<td>Medical Devices</td>
<td>18</td>
</tr>
<tr>
<td>Diagnostic Tools</td>
<td>27</td>
<td>Diagnostic Tools</td>
<td>24</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
<td>Other</td>
<td>4</td>
</tr>
</tbody>
</table>

Source: Monitoring Information from Innovate UK and the Medical Research Council

4.2 Assessed Quality of Applications

The quality of all applications to the Biomedical Catalyst has been assessed by a combination of independent assessors and peer reviewers, with Confidence-in-Concept, Early, and Late Stage applications given further scrutiny by the CiC panel, the DPFS panel, or the MAC. This section provides an analysis of the outcomes of the project assessment process, focusing mainly on the Feasibility, Early and Late Stage awards made through the programme (as a proxy measure of the quality of the applications received).

4.2.1 Independent Assessments

A total of 417 applications for Feasibility Studies, and full-stage applications for Early and Late Stage awards were assessed by the independent assessors engaged by Innovate UK. The figure below shows the distribution of applications by the average score received through the assessment process. Forty-five per cent of feasibility applications received an average score in excess of 70 per cent, as did 92 per cent of applications for both Early and Late Stage awards (note that the EOI process would have filtered out applications that were judged to be of lower quality, so comparisons should not be made between scores for feasibility and other types of award).

- **Funding decisions based on independent assessments**: Eighty-five of the 220 applications for the feasibility award were funded on the basis of the independent assessment (a success rate of 39 per cent). In rounds 1 to 3, Early Stage awards were also awarded on the basis of the judgements made by independent assessors (with marginal bids subject to a moderation process). Over this period, 36 of the 63 applications were approved by Innovate UK (a success rate of 57 per cent).

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25 Monitoring information on the scores received at the EOI stage was not available.
• **Progression to the Major Awards Committee**: The scores received through this process were used to determine which Late Stage applications received by Innovate UK (and Early Stage applications from round 4 onwards) would be scrutinised in more detail by the MAC. Of the 88 full Late Stage applications that received an independent assessment, 77 were passed through to the next stage (88 per cent). Of the 46 relevant full stage early applications, 42 progressed to the MAC (91 per cent). As such, the MAC provided scrutiny of the large majority of full stage applications received by Innovate UK and a few of the applications were declined on the basis of the independent assessment alone.

**Figure 4.1 – Distribution of Independent Assessment Scores: Feasibility Studies, Early and Late Stage awards (Innovate UK only)**

Source: Monitoring Information from Innovate UK

4.2.2 **Major Awards Committee (MAC) and Developmental Pathway Funding Scheme (DPFS) panel**

The DPFS considered and scored all Early Stage applications to the Biomedical Catalyst led by academics, while the MAC considered and scored all Early Stage applications that were led by firms, and all Late Stage applications (led by firms or academics). Both panels used the same scoring system, and the distribution of scores given is broken down in the figure overleaf. In terms of headline measures:

• **DPFS**: The DPFS panel considered a total of 143 applications over the six rounds under consideration. Forty three of these applications were approved for funding (a success rate of 30 per cent).

• **MAC**: The MAC considered a total of 149 applications, including 42 Early Stage applications led by firms (of which 11 were successful), 77 Late Stage applications led by firms (of which 31 were successful), and 30 Late Stage applications led by academics (of which 13 were successful). The corresponding success rates were 26, 40 and 43 per cent respectively.

As illustrated in the figure below, the low success rate of Early Stage bids at the MAC appears to be linked to the scores given at the panel, rather than by rationing caused by an oversupply of high-scoring bids (almost 75 per
cent of these bids received a score of less than 7 at the MAC, compared to 61 per cent of Late Stage awards led by firms).

Figure 4.2 – Distribution of Mean Scores Given by MAC and DPFS panels

Source: Monitoring Information from Innovate UK and Medical Research Council

Focusing on applications received by Innovate UK, the figure below sets out the correlation between the scores received by firm-led applications, following the independent assessment, and the scores given to the same applications by the MAC. While there is a positive correlation between the two sets of scores, this relationship is weak with many applications receiving substantially higher or lower scores than those anticipated after the independent assessment. This has led to some significant changes in the ranking order of applications following the panel. Figure 4.4 illustrates that the correlation between the peer review scores received by applications to the MRC, and scores given by the DPFS and MAC panels, is stronger.
Figure 4.3 – Mean Scores at MAC and Independent Assessment Scores (Innovate UK, full stage applications only)

Source: Monitoring Information from Innovate UK

Figure 4.4 – Mean Scores at MAC and DPFS panels and Peer Review (MRC, full stage applications only)

Source: Monitoring Information from MRC
4.3 Characteristics of Funded Projects

A total of 255 projects were funded over the first six rounds of the Biomedical Catalyst, with a funding commitment of £200m to projects with a value of £300m. On average, 31 projects were funded in each round, although the number of projects funded in each round decreased (in absolute numbers, not taking into account the changing number of strands open in each round) over the period as a whole, this was a similar case for the total value of grants awarded. The table below provides a more detailed breakdown of the project portfolio.

Table 4.3 – Number of Projects and Funding Committed (rounds 1 to 6)

<table>
<thead>
<tr>
<th></th>
<th>Firm-led</th>
<th>Academic-led</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant value</td>
<td>Project value</td>
<td>Project value</td>
<td>Projects</td>
</tr>
<tr>
<td>Confidence-in-Concept</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Feasibility Studies</td>
<td>11.2</td>
<td>15.2</td>
<td>83</td>
</tr>
<tr>
<td>Early Stage</td>
<td>60.4</td>
<td>108.2</td>
<td>47</td>
</tr>
<tr>
<td>Late stage</td>
<td>44.8</td>
<td>90.7</td>
<td>33</td>
</tr>
<tr>
<td>Total</td>
<td>116.3</td>
<td>214.1</td>
<td>163</td>
</tr>
</tbody>
</table>

Source: Monitoring Information from Innovate UK and the Medical Research Council

4.3.1 Project Characteristics

Management information for the whole set of Biomedical Catalyst projects (usefully compiled by the Medical Research Council) provides information on a range of project characteristics:

- **Duration**: Around half of the projects (46 per cent) were scheduled to last between 10 and 20 months, with a further 20 per cent scheduled to last between 20 and 30 months. There are also 38 projects (15 per cent) expected to last around, or just over, three years. Feasibility Studies tend to be the projects of shortest duration, and firm-led projects tend to have shorter durations than those that are led by academics.

- **Collaboration**: The majority (68 per cent) of all awarded projects within the Biomedical Catalyst programme were single applicant projects (i.e. did not have a formal collaborator involved). This held true across academic and industry-led projects, and across all types of awards.

- **Modality/technology type**: Drug development was the largest area of activity for funded projects, accounting for over one-third of the projects and almost half of the funding committed (48 per cent). The next

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26 It is anticipated that this trend was driven by budget constraints - there was no indication that appetite for funding had fallen over the course of the programme, or that the average quality of project had fallen (as measured by project appraisal score).

27 As grants to academics are given to the lead organisation and data on formal partnership within the programme is not recorded in full, this number may underestimate the overall level of collaboration. As indicated in the next section, over 75% of academic applicants were collaborating with an academic or industry partner with 20% working with an academic outside their organisation.

28 Drug development projects consisted mainly of small molecule projects (64%), antibodies (17%), proteins/peptides (16%) and other drugs (4%). With respect to disease area, most of these projects targeted cancer, (29%), infection (15%), inflammatory and immune system (7%) musculoskeletal (7%) and neurological (7%) and others (less than 5%).
largest area, in terms of the number of projects, was diagnostic tools with 57 projects (22 per cent), although a larger share of the budget has been allocated to cellular and gene therapy (these projects are associated with the highest average cost at £1.3m). There were no substantial differences between the profile of funded projects and the profile of applications received.

- **Disease area**: The most prevalent disease areas for funded projects to be working on were cancer (50 projects), infections (48 projects) and neurological conditions (22 projects). There were also more than ten projects relating to musculoskeletal conditions (14) and cardiovascular disease (11 projects). This reflected the disease areas which submitted the most outline applications to the Medical Research Council over the period: cancer (96 applications, 18 per cent), infections (72 applications) and neurology (68 applications).

### 4.3.2 Applicant Characteristics

There have been 191 unique participants in Biomedical Catalyst projects, with 172 acting as a lead organisation for at least one project. The majority of participants (70 per cent) led on a single project, although 39 led on two or more. The largest number of projects led by a single institution was an academic institution (14 awards), and all institutions leading or receiving four or more awards were universities. Three of the organisations leading three awards were biotech companies whilst a fourth biotech company received three awards but did not lead on all of them. Thirty nine organisations acted as a co-applicant on projects and 19 of these took part in the Biomedical Catalyst as co-applicants. Eight organisations, all universities, were a co-applicant on more than one project.

As illustrated in the table below, 77 per cent of funded organisations were private companies, receiving over half the Biomedical Catalyst funding (53 per cent). A further 46 per cent of funding was allocated to universities, which, while representing only 19 per cent of funded organisations, received much larger grants on average than other types of organisation (in part reflecting the award structure constructed around state aid rules, which limits funding allocations to non-academic research). The remaining awards were made direct to research organisations, charities and NHS trusts, making-up seven organisations in total.

#### Table 4.4 – Funded Organisation by Type

<table>
<thead>
<tr>
<th>Type</th>
<th>Number of organisations funded</th>
<th>Total funding committed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private company</td>
<td>147</td>
<td>£107m</td>
</tr>
<tr>
<td>HEI</td>
<td>37</td>
<td>£92m</td>
</tr>
<tr>
<td>Research institute</td>
<td>3</td>
<td>£1.9m</td>
</tr>
<tr>
<td>NHS</td>
<td>2</td>
<td>£384k</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>£135k</td>
</tr>
<tr>
<td>Total</td>
<td>191</td>
<td>£201m</td>
</tr>
</tbody>
</table>

Source: Monitoring Information from Innovate UK and the Medical Research Council

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29 A significant number of the academic awards will have NHS partners/components within them that would not be captured in the award data.
4.4 Project Spending

The two organisations have different systems for monitoring the finance of projects. These differences are mainly driven by the characteristics of grant recipients. The Medical Research Council is dealing with universities with whom they have an established system for receiving grants, and corrections to projects terminating early or to marginal supplementary spending are made at the end of the academic year. Innovate UK, on the other hand, funds SMEs which have gone through the due diligence checks but are receiving funding based on the delivery of expenditure set out in the project plan. Innovate UK MOs therefore monitor and approve spending which results in more detailed current spend figures updated on quarterly basis.

Innovate UK has - as at the end of February 2015 - committed a total of nearly £102m to its Biomedical Catalyst projects. According to Innovate UK monitoring data, closed projects had an overall underspend of 3 per cent compared to the committed funds. Projects with one final claim to submit had on average spent 85 per cent of the committed funds and live projects overall had used about 36 per cent of their budgets. Projects that terminated were on average more than half way through their committed spending. The full profile of spending is provided in Table 4.5:

Table 4.5 – Project spending compared with funds committed – Innovate UK only

<table>
<thead>
<tr>
<th></th>
<th>Spent (£m)</th>
<th>Committed (£m)</th>
<th>Rate of grant utilisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Closed</td>
<td>13.2</td>
<td>13.6</td>
<td>97%</td>
</tr>
<tr>
<td>Final Claim</td>
<td>0.1</td>
<td>0.2</td>
<td>85%</td>
</tr>
<tr>
<td>Live</td>
<td>31.6</td>
<td>87.4</td>
<td>36%</td>
</tr>
<tr>
<td>Offer Letter Sent</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Terminated</td>
<td>0.5</td>
<td>0.7</td>
<td>63%</td>
</tr>
<tr>
<td>Total</td>
<td>45.4</td>
<td>101.9</td>
<td>45%</td>
</tr>
</tbody>
</table>

Source: Monitoring Information from Innovate UK, February 2015.

The Medical Research Council has provided only summary data on expenditure, combining payments that have been made and commitments for future years. This information is summarised in table 4.6 overleaf (and suggests that £46m was spent by the end of 2014/15, nearly half of the total funds committed).
Table 4.6 – Medical Research Council expenditure and funding commitments

<table>
<thead>
<tr>
<th>Year</th>
<th>Project expenditure / Commitment projections for the future years (£m)</th>
<th>MRC Finance Payments total for Biomedical Catalyst to Innovate UK (£m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012/13</td>
<td>7.1</td>
<td>0.9</td>
</tr>
<tr>
<td>2013/14</td>
<td>18.2</td>
<td>2.2</td>
</tr>
<tr>
<td>2014/15</td>
<td>16.7</td>
<td>1.2</td>
</tr>
<tr>
<td>2015/16</td>
<td>19.4</td>
<td>0.8</td>
</tr>
<tr>
<td>2016/17</td>
<td>15.0</td>
<td>0.1</td>
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<tr>
<td>2017/18</td>
<td>8.4</td>
<td>-</td>
</tr>
<tr>
<td>2018/19</td>
<td>4.0</td>
<td>-</td>
</tr>
<tr>
<td>2019/20</td>
<td>1.4</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td>96.5</td>
<td>5.2</td>
</tr>
</tbody>
</table>

Source: Monitoring Information from the Medical Research Council, February 2015.

4.5 Project Delivery

This section provides an analysis of the information available on project delivery.

4.5.1 Project Progress

As at March 2015, over half of all approved applications from rounds 1 to 6 were live (note that this information excludes the Confidence-in-Concept awards). Sixty-one projects have been completed (the majority of which were Feasibility Studies), of which only one was an academic-led project. Eighteen projects had not yet begun, and eleven projects (5%) had been terminated early. The main reasons for project termination included:

- Successful research projects closed early due to results of therapy not significantly better than placebo or current best practice treatment in a clinical trial (i.e. for efficacy reasons)
- Dataset did not support project hypothesis
- Toxicity results made project continuation unfeasible

Of the ten terminated projects for which information is available, all but one were from competition year 2013; three were Feasibility Studies; one was led by an academic, one by a research organisation and the remainder by limited companies (four micro, three small and two medium-sized). The spread of project areas involved appears to reflect the overall proportion of technologies across funded projects and applications.

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30 A number of firm-led projects that terminated early did so as a result of losing matched industrial funding... terminating before they started.
Table 4.7 – Number of Projects by Project Status (rounds 1 to 6)

<table>
<thead>
<tr>
<th></th>
<th>Firm led</th>
<th></th>
<th>Academic led</th>
<th></th>
<th>Total</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Percent</td>
<td>Number</td>
<td>Percent</td>
<td>Number</td>
<td>Percent</td>
</tr>
<tr>
<td>Closed</td>
<td>60</td>
<td>37</td>
<td>1</td>
<td>2</td>
<td>61</td>
<td>28</td>
</tr>
<tr>
<td>Live</td>
<td>86</td>
<td>53</td>
<td>43</td>
<td>77</td>
<td>129</td>
<td>59</td>
</tr>
<tr>
<td>Offer Letter Sent</td>
<td>7</td>
<td>4</td>
<td>11</td>
<td>20</td>
<td>18</td>
<td>8</td>
</tr>
<tr>
<td>Terminated</td>
<td>10</td>
<td>6</td>
<td>1</td>
<td>2</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>163</td>
<td>100</td>
<td>56</td>
<td>100</td>
<td>219</td>
<td>100</td>
</tr>
</tbody>
</table>

Source: Monitoring Information from Innovate UK and the Medical Research Council

The Medical Research Council monitors the risk status of its project portfolio against a Red, Amber, and Green (RAG) monitoring system. This data suggests that of the 43 live projects, 36 were deemed low risk at March 2015 (84 per cent), with 7 as amber risk (16 per cent). Innovate UK also monitors projects using a RAG status.

4.5.2 Project Outputs

Project outputs are monitored through project closedown reports, end reports and ResearchFish data for Innovate UK and MRC respectively. Projects funded by the Biomedical Catalyst are not contracted to deliver defined outputs (such as jobs created) and as such do not have targets against which the progress of the project portfolio can be judged - in part because those outputs would be realised (often far) beyond the lifetime of the award. However, the Medical Research Council and Innovate UK, while the questions asked in each monitoring system are somewhat different, do monitor project achievements through the ResearchFish’s monitoring system and end reports and projects closedown reports respectively (the latter reports completed by the applicant). The data suggest the following:

- **Publications:** The ResearchFish system requires applicants to provide information on any publications that have been prepared as a consequence of the project. This data suggests some 103 publications have resulted from the supported projects with an academic component (of which 39 have resulted from the Confidence-in-Concept awards). Innovate UK monitoring information suggests that 3 of the 43 projects resulted in publications in the academic press.

- **Funding:** Information captured in ResearchFish suggests that academic applicants had raised an additional £41.5m in grant funding from other sources (almost exclusively - 90% - reported by Confidence-in-Concept awards, and largely from charitable or public sources). A total of 5 of the 43 Innovate UK applicants, who completed project closedown reports, detailed that they had secured additional funds (a total of £800,000, mainly from existing investors) since the award. Although, the majority of other respondents reported that their contributions to project costs had exceeded budget. Programme monitoring officers have collated a minimum of £119m of post award investment in companies through share issues (as at data collection period in winter 2014), financing rounds and licencing deals.

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31 The project status monitoring database does not contain information on the status of all academic-led projects.

32 This information is not independently validated, and has not been completed by all successful applicants (making it difficult to determine how far these results represent a partial record).
- **Collaboration:** ResearchFish data suggests that a total of 129 new collaborative relationships have been formed by academic applicants since the start of the Biomedical Catalyst. 50 per cent of these relationships were formed with other universities and 35 per cent with the private sector (although, some 60 per cent of projects were reported to not have produced any new collaborations to date, though this is not unexpected as a high proportion of projects were not developed as collaborative projects). This number is relatively high considering the low proportion of projects which started as collaborative ventures. A high proportion of these new collaborative relationships (108 of 129) were reported by Confidence-in-Concept funding recipients. Innovate UK explores how collaborations came about by asking respondents to report if they had engaged with their collaborators through the Connect community or the Knowledge Transfer Network (however, just one of the 43 respondents reported that they had).

- **Tools and databases:** ResearchFish data indicates that academic applicants developed 21 new tools (including 10 models of symptoms or mechanisms, and five technology assays or re-agents), 2 biological samples, 2 cell lines and 2 new databases or improvements in infrastructure or computer algorithms.

- **Intellectual Property:** Thirteen instances of IP generation were reported by academic applicants, including 11 patent applications, a registration of a trademark, and one copyright. In three cases, the applicants reported that they had licensed the IP. Nine of the 43 Innovate UK funded projects reported that they had filed a patent application, of which two reported they had entered into licensing deals.

- **Products:** Academic applicants reported the creation of 37 new products, of which 15 were at initial development stages, 19 were in the process of clinical or non-clinical refinement, and three were at the stage of early clinical assessment. Three of the 43 Innovate UK funded projects reported that they had finalised products at the end of the project.

- **Spin-outs:** Six spin-outs were reported by the academic applicants (five of which emerged from Confidence-in-Concept awards). It is not possible however to differentiate between spin-outs that pre-date the Biomedical Catalyst, where they were created in order to apply for Biomedical Catalyst funding, and those which arose as a consequence of progress in funded projects.

- **Jobs:** The 43 Innovate UK applicants reported that they had created a total of 16 full-time jobs and nine part-time positions over the duration of the project.

### 4.6 Summary

- **Demand for Biomedical Catalyst funding:** Over the first six rounds of the programme, over 1,000 EoIs or outline bids and 600 full applications have been received for the Biomedical Catalyst funding. The total value of funding requests was four times the level of the funding available (suggesting that Innovate UK and the Medical Research Council have faced no substantial challenges in committing funds). The profile of applications over the first six rounds broadly reflects the profile of the targeted industry (and did not suggest that any particular subsectors are overrepresented relative to their share of total economic output, though medical devices were underrepresented relative to their share of the number of active enterprises). It is more difficult to judge this representation relative to the market potential of nascent subsectors (as objective data is more difficult to acquire). There is no evidence of any change in overall demand for the scheme over time.

- **Project selection process:** A total of 255 projects have been approved in the first six rounds, including 36 Confidence-in-Concept awards, 83 Feasibility Studies, 90 Early Stage projects, and 46 Late Stage projects. Success rates for full applications vary, though in general a high proportion of applications are declined. The project selection process has involved the commitment of £200m of public funds (approximately evenly spread across academic and firm led bids) to projects with a total value of £300m.

- **Innovate UK Independent assessments and MAC scores:** Although on average only 37.1 per cent of EoI applicants were invited to submit Full Stage application in the Early and Late Stage competitions, few of those submitting Full Stage application bids have not passed through to the MAC. There is little correlation between
the scores received at the independent assessment stage and the scores received at the MAC (often leading to substantial changes in the rank order of applications). This raises questions as to how far the independent assessment process adds value to the project selection process, beyond the feedback provided to applicants to enable them to prepare for the presentation of their project to the MAC (the effectiveness of this feedback is examined in the following section).

- **Funded projects:** The majority of funded projects were focused on the development of new drugs, diagnostic tools and cell or gene therapies and were, most frequently, targeted at cancer, infection and neurological conditions. Projects tend to be delivered by single organisations rather than in collaboration, with the majority of projects planned to be delivered over a 10 to 20 month period (with academic-led projects tending to be associated with longer timescales than those led by firms).

- **Project delivery:** Around 30 per cent of the projects funded over rounds 1 to 6 have completed (though these were largely Feasibility Studies), with the majority still live. A small proportion of projects have terminated (largely due to concerns either relating to toxicity, efficacy, or the loss of matched funding), though the data available on the risk profile of current projects do not at this stage suggest any reasons for concern.

- **Project outputs:** Management information suggests that projects have delivered a wide range of outputs, though at the time of writing this report, it is difficult to make an assessment of how far this is suggestive of strong or weak performance, as no targets for duration of the project or beyond are defined prior to the commencement of projects (and the majority of projects are still in progress). The information available on outputs is also limited, firstly by its completeness, (for example, data on Innovate UK projects is only available on the closure of a project, with no on-going quantitative monitoring of the delivery of scientific research results over the course of the project) and then its consistency (it is highly challenging to aggregate Innovate UK and Medical Research Council data to provide a consistent aggregate view of the results delivered by projects).
5 Process Evaluation

This section presents the findings from the process evaluation research. It reviews the extent to which the programme has been successfully set up to achieve the objectives set outlined in section 2, focusing on performance around marketing and communications, the application process, activity to assess, review and select applications, as well as focusing on the contracting and monitoring operations involved with the delivery of the Biomedical Catalyst.

5.1 Marketing and Communications

5.1.1 Effectiveness at Raising Awareness among Target Groups

The delivery partners have collaborated to deliver a broad range of marketing and communications activities. The announcement of the programme by the Prime Minister in December 2011 appears to have immediately raised awareness of the scheme. This was followed up with a broad programme of primary outreach activities to raise awareness of the Biomedical Catalyst including:

- Launch events in London and Edinburgh organised by the Lead Technologist at Innovate UK
- Use of Knowledge Transfer Networks to notify their network about calls for funding
- The Medical Research Council and Innovate UK websites
- Innovate UK and the MRC working collaboratively with industry associations in the pharma and biotech sectors to raise the profile of the programme
- MRC engagement in a variety of direct awareness-raising activities building on the four years of DPFS programme including a translational research road show, contacting university research offices receiving Medical Research Council funding, and direct approaches to elicit CiC applications and,
- University visits – annual visits to the 15-20 most ‘important’ institutions, and additional visits where requested (typically following unsuccessful applications) to raise the profile of the programme.

Additional one off outreach activities included:

- A webinar hosted jointly between MRC and Innovate UK via the Innovate UK website which was seen as a particular success by the hosts
- A joint MRC and Innovate UK investor event in 2012
- An event to publicise the Biomedical Catalyst at the Cell Therapy Catapult and
- Other one-off briefing events including a competition briefing event held by Innovate UK in Leeds in June 2014, a related med-tech workshop and a digital health focused event in December 2013

The delivery of this programme of activity appears to have been received positively by applicants and stakeholders. An issue was however identified by a number of applicants and stakeholders regarding the marketing of the Biomedical Catalyst on the new .gov.uk website. There was a concern that some of the visibility of the Biomedical Catalyst had been lost in the transition to the standard platform for all government communications (Gov.uk).

Evidence from the survey of applicants illustrates how applicant organisations first became aware of the scheme. Direct contact with either Medical Research Council or Innovate UK (Medical Research Council / Innovate UK website, Medical Research Council / Innovate UK event, or KTN) was the source of initial information for 21 per
cent of applicants. The Medical Research Council website was especially important for informing academic applicants. However, it appears that informal networks (word of mouth, colleagues or collaborators) were the most important overall route through which applicants had become aware of the Biomedical Catalyst.

Figure 5.1 – Source of initial awareness of the Biomedical Catalyst

Source: Survey of applicants, figures in brackets reflect the effective sample size

Stakeholders identified that the availability of non-diluting funding and large individual awards had made the scheme an easy one to communicate to potential applicants. A large proportion of the stakeholders consulted felt strongly that the Biomedical Catalyst was well known amongst those engaging in drug discovery and among biotech firms, but that additional communication activities would be required to boost awareness among other areas of the life sciences sector such as health analytics. One applicant suggested to the study team that knowledge of the programme was ‘in the air’, implying a very high awareness among the drug development communities within which he operates. This is reinforced by the quantitative data set out in the preceding section: the evidence suggests there are around 800 active SMEs in the relevant sub-sectors, approximately equal to the number of EOIs received by Innovate UK (the majority of which were in this general area). Equally, applications were received from almost all academic institutions receiving Medical Research Council funding (in any form).

The stakeholder consultations did however identify a number of ways in which communications about the Biomedical Catalyst could be developed. A small number of those consulted suggested that the communications effort had been too focused on the south-east and the ‘Golden Triangle’ (Cambridge, London and Oxford) with this coming at the cost of awareness in the north of England and Scotland. Additionally, while it appears that the marketing and communications efforts have been particularly effective within the biotech area, but awareness is lower in the rest of the sector (again, reflected in the ratio of active SMEs to applications received), such as those developing diagnostic tools or products in the digital health space.

To some extent, this result could be expected. Stakeholders identified this market segment as a more difficult group to reach, given that its firms were not thought to be broadly represented by a single trade body. While the Association of British Healthcare Industries is an important organisation in this space, its membership represents
a small proportion of the market. Because many of the opportunities in this area appear to be coming from the implementation of broad platform technologies with multiple applications to health challenges, it was suggested that many firms in this space do not necessarily recognise that they play a role within the life sciences sector. However, a number of stakeholders suggested that better engagement with these groups could help to boost the impact of the Biomedical Catalyst. As noted in section 3, it was suggested that many of these emerging diagnostic and digital areas represent fast-growing markets but are seen as less investable markets than traditional drug development. This implies the potential presence of additional market failures (including broader co-ordination problems) and an additional economic rationale for public investment (though not necessarily in the form of a Catalyst).

Finally, despite strong working relationships between the Medical Research Council and Innovate UK, there is an opportunity for both bodies to further promote each other’s programmes. Case study interviews show that some applicants are making an informed decision between applying as an academic or through a company (often a university spin-out). The survey of applicants also suggests that four per cent of lead applicants from firms consulted a university or university technology transfer office when submitting their application. This implies that it is not necessarily possible to draw a hard line between the two strands of the programme. However, many applicants and some stakeholders interviewed through the course of our research were not aware of the two routes to funding. As a result there may be lost opportunities to capitalise projects originating in academia owing to funding rules.

The Biomedical Catalyst has developed as a strong brand on its own. In interviews with academic applicants and stakeholders with an academic background the DPFS was also identified as a strong brand and cited by these individuals more frequently than the Biomedical Catalyst. The establishment of a single website or mirrored pages on the Medical Research Council and Innovate UK sites as well as a single shared logo for the programme (which exists but is used very little) could help to increase transparency here and ensure funding opportunities are communicated as clearly as possible.

5.1.2 Communicating the Objectives of the Biomedical Catalyst

The policy objectives of the Biomedical Catalyst are to support the pull-through of academic research into the commercial sector and the growth of the life sciences sector by responding to market failures associated with the commercialisation of intellectual property. Overall, it appears that the Biomedical Catalyst has been highly successful in communicating these objectives as well as a general understanding of the types of projects which could expect to secure funding.

The applicant survey confirms that Innovate UK and the Medical Research Council were active in supporting applicants ahead of their submissions to help ensure they understood these requirements. Almost all applicants had accessed on-line information and guidance describing the Biomedical Catalyst application process (regardless of the website issues discussed above). The majority had contacted either the Medical Research Council or Innovate UK for further guidance. Seventy per cent had attended an application briefing event for the Biomedical Catalyst. Approximately one fifth of applicants had received one-to-one support from a Knowledge Transfer Network to support the development of their applications.
Figure 5.2 – Sources of guidance used prior to submitting applications

Source: Survey of applicants, figures in brackets reflect the effective sample size

This appears to have translated into a highly informed group of applicants. Eighty five per cent of applicants strongly agreed or tended to agree that the information provided prior to application made the objectives of the Biomedical Catalyst clear and more than 70 per cent of applicants agreed that the criteria against which applications would be assessed were made clear. Figure 5.3 also indicates that for the majority of applicants, the overall application process, the likely timelines for due diligence, monitoring requirements and payment terms were all successfully communicated prior to application.
Figure 5.3 – Extent to which applicants tended to agree or strongly agreed that the information used clearly explained each of the elements

Source: Survey of applicants, figures in brackets reflect the average effective sample size

A small number of stakeholders suggested that some groups of potential applicants within the broad sector involved in developing products for improving human health do not appreciate that support for their activities is an objective of the scheme. Furthermore, one of the stakeholders noted that one specific subsector, med-tech, might be ‘put off’ by the name of the programme.

Finally, case study evidence suggests that objectives of the early CIC awards were initially communicated relatively loosely and this is visible in the substantial diversity of approaches that the five case-studied institutions chose. Consequently, a number of the universities receiving CIC awards suggested they did not receive clear messages about the monitoring requirements that would be expected of them.

5.1.3 Working with Investors

An important objective of the Biomedical Catalyst was the development of the UK life sciences investment market. By offering large scale investments in the life sciences sector which do not require an equity stake it was hoped that potential investors would be enticed into the UK life sciences market from other sectors and from other countries. In the short term, the scale of this effect will depend at least partly on the effectiveness of communications with investors and the extent to which investors are aware of the scheme.

Stakeholders identified a generally high level of awareness amongst investors of the Biomedical Catalyst. This was thought to be particularly true of investors who were focused on drug discovery. Here the stakeholders and individual investors interviewed indicated that awareness of the Biomedical Catalyst would be close to universal. As expected, given the discussion in section 5.1.1 above, investors in other areas of life sciences were thought to be less aware of the Biomedical Catalyst. It was suggested that business groups in the area of medical devices, for example, had been less involved in the development and marketing of the Biomedical Catalyst than those in biotech.
An aspiration of the Biomedical Catalyst is to help overcome an information-related market failure within the life sciences sector. By supporting only projects which have a strong scientific basis and represent significant commercial opportunity it is hoped that the Catalyst will offer a signal of project quality to the investment market. It was hoped that securing a grant from the Biomedical Catalyst would produce a ‘halo effect’, to help attract further investors to support these projects. A number of successful applicants identified this effect. Several companies felt that they had been able to secure additional private investment (as well as other benefits such as attracting staff) because they had secured Biomedical Catalyst funding. The study team interviewed one investor who was specifically focusing his search efforts on Biomedical Catalyst grant recipients, indicating that this is working to some extent; the impact of this effect is explored in greater depth in section 6. However, applicants more readily identified the effect that additional investment was secured because investment propositions were financially de-risked, due to the presence of the grant on company balance sheets. This effect was acknowledged to be of higher importance than the robust nature of the project selection process.

It was suggested to the study team that it may be too early to appraise the effectiveness of communications with investors about the Biomedical Catalyst. One stakeholder suggested that successful investor exits (i.e. profitable disinvestments) from companies which have received Biomedical Catalyst support will help to market the programme to other investors. It was suggested that these exits could be expected to start happening in the next 12 months, and may significantly boost the profile of the programme among potential investors.

5.2 Application Process

5.2.1 Ease of Use

Applicants to the Innovate UK and the Medical Research Council typically found the application forms straightforward to complete. They were generally seen as following a clear pattern matching other similar schemes. It was clear from interviewing applicants that they were all highly experienced in submitting funding applications (several suggested that they were able to apply by making minor adaptations to submissions for other schemes). Nevertheless, several applicants suggested that the process of applying to the Biomedical Catalyst included fewer barriers and administrative complexities than they had experienced with grant applications previously. They felt that the forms required were more straightforward than those used in other schemes. Applicants felt that overall the process was asking the ‘right’ questions and encouraging a high quality of applications.

- **Confidence-in-Concept**: This generally high level of satisfaction was felt across university applicants to Confidence-in-Concept awards, academic Early and Late Stage applicants and firms. Applicants to the Confidence-in-Concept awards did however express some reservations about the need to re-apply to the scheme every year. They felt that this increased the administrative burden of the scheme, and meant that some institutions were not maximising the opportunity presented by the scheme to invest in their infrastructure support for translational research. For example, one case study institution had found it difficult to justify internal investments in institutional support for their internal CiC process because the future of the funding was uncertain. Increasing the length of each award beyond eighteen months (or even awarding CiC funding on an on-going basis, guided by past performance), and offering confidence that CiC awards will be an on-going funding priority were suggested as ways to mitigate these issues. One applicant to the CiC felt that they were being encouraged to support different areas to the ones that formed their application in the previous year in order to secure on-going CiC awards from the panel, even though this evolution was not a formal requirement.

Some of the case study interviewees saw the process of developing and articulating a new focus for each year’s application as increasing the administrative burden, and potentially distracting from continued support for the most productive areas of activity.
• **Innovate UK**: Firm applicants did identify some modest technical issues with filling in the application forms such as the inability to run spelling checks within the submission system. Some applicants to early rounds had found the application form too short to fully explain their plans. It was suggested that this had resulted in several assessors misinterpreting or misunderstanding proposals. However, the increase in the length of the forms from 8 to 24 pages ahead of round 4 responded to this issue and appears to have addressed these concerns.

5.2.2 Guidance Materials and Support

Both Innovate UK and Medical Research Council publish guidance materials for applicants.

• **Medical Research Council**: The Medical Research Council shares with applicants the BMC:DPFS assessment criteria applicant’s handbook, guidance for outline stage BMC:DPFS applicants and the BMC:DPFS outline case for support form. None of the guidance materials however explicitly describes the different routes that the applicant may take once their application has been peer reviewed (i.e. DPFS vs MAC). The application process is managed via Medical Research Councils standard application portal Je-S and its standard helpdesk provides support. Successful applicants from the outline stages are invited to a Medical Research Council organised workshop to provide further guidance to support the development of their applications.

• **Innovate UK**: The guidance documents for firms cover broadly the same topics as the Medical Research Council guidance but do not cover more academically oriented issues such as ethical considerations of research or before the use of specific models in testing. The Innovate UK guidance document clearly highlights the competition process and describes each of the steps including the MAC. Innovate UK has made a number of revisions to the application form over the rounds.

As identified in figure 5.2 above, almost all applicants have made use of guidance materials provided by the Medical Research Council and Innovate UK, and 60 per cent had contacted either the Medical Research Council or Innovate UK for further guidance or support. The guidance materials and support offered by the Medical Research Council and Innovate UK was viewed positively by applicants. The application workshops offered by the Medical Research Council appear to have been particularly well received. Academic applicants suggested that the highly tailored and interactive nature of these guidance sessions had helped them to develop their proposals, and to understand what a good application to the Biomedical Catalyst would look like. One very experienced translation research expert did feel, however, that these could be better focused on less experienced applicants.

Considering the application process as a whole, the MAC appears to have been the most contentious stage for applicants, especially for firms. There is a suggestion that further guidance and support could have helped some applicants to prepare for this stage. Some of the consulted academic applicants were unaware of the reasons for being directed through the MAC as opposed to the DPFS panel. The survey of firm and academic applicants identified mixed, and to some extent polarised, views on the extent to which clear instructions were received about how to best prepare for the panel. Figure 5.4 indicates that approximately 20 per cent of applicants strongly disagreed with the suggestion that they had received clear instructions on how to prepare for the panel. This guidance was updated prior to round six. The survey included only a small number of firms who had presented at the MAC in round six. However, four of these six respondents reported that they either tended to disagree, or strongly disagreed with the statement that they had received clear instructions on how to prepare for the panel.

The sample includes only a small number of academics who participated in the MAC, but it appears that dissatisfaction with pre-MAC guidance was a more significant issue for firms than academics (20 per cent of academic applicants disagreed with the statement that they had received clear instructions on how to prepare for
the panel compared to 50 per cent of firm applicants). Questioning at the MAC is heavily science oriented, and this particular concern of firms may reflect the fact that this style of approach may be more akin to the environment of a defence of an academic position than a typical business fundraising process. However, many of the firms contacted as part of the research had an academic background, and analysis of applicant firms conducted by the MRC indicates that approximately half of them originate from academic spin-outs. This experience would have mitigated this effect. Nevertheless, from the qualitative evidence it appears that the most experienced academic applicants appear to prize most highly the ability of the MAC to interrogate projects. Perhaps unsurprisingly, attitudes towards the guidance received ahead of the MAC interview varied between successful and unsuccessful applicants with those successful in securing grants from the Biomedical Catalyst expressing less concern about the guidance received.

**Figure 5.4: Percentage of applicants who presented to the MAC who felt they had received clear instructions on how to prepare for the panel**

![Bar chart showing percentage of applicants who felt they had received clear instructions on how to prepare for the panel.](image)

Source: Survey of Applicants

A number of stakeholders suggested that applicants who were requested to present to the MAC had a generally less positive view of the application process. However, a comparison of responses between those who did and did not attend a MAC session indicates only a modest difference between these two groups.
Interviews with applicants and members of the MAC identified two areas in which the guidance offered to applicants in advance of participating in the MAC could be improved:

- There appears to be confusion amongst applicants with respect to what determines whether an applicant would be expected to present their application to the MAC. For example one applicant had reduced the scale of their project in order to avoid the need for attending a MAC, even though this is not the decisive criterion. The expectation that applications which are closer to market, regardless of scale, will be required to present to the MAC is now communicated at the applicant workshop and on the revised website.

- A number of applicants expressed concern about a misalignment between the issues identified by assessors and the points raised by committee members in the MAC. Several applicants went to the session with confidence that they had received largely positive feedback from assessors and had prepared thoroughly to respond to the issues identified. However, they had found the discussion at the MAC focused on different issues. Others expressed confusion about whether their presentation to the MAC should include a response to feedback from assessors or a full overview of their application.

5.2.3 Costs to Applicants

The survey of applicants offers a snapshot of the costs associated with submitting an application to the Biomedical Catalyst. Outline applications appear to have required an average of 160 hours of staff time to prepare, and full stage applications more than 260 hours. Applications from academics have taken longer to prepare, but there was little difference in the time required to prepare what were ultimately either successful or unsuccessful applications. Valuing this time at the median average earnings for biological scientists and

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33 This is consistent with the general Standard Cost Model framework, though the use of average earnings as a proxy measure of the productivity foregone will likely overstate the costs involved (as marginal productivity will be lower than average productivity under assumptions of diminishing marginal returns).
bioclimates in 2014 (£18.9934), this gives an approximate cost per EOI of £2,400 and cost per outline bid of £4,500. Full stage applications are estimated to cost firms £4,000, and academics £7,400. For those making it to the MAC, an additional £800 and £1,300 was incurred by academics and firms respectively in preparation for the interview. Some stakeholders indicated concerns about the ability of small, independent companies to resource applications (though the burdens to applicants are not high given experiences of other schemes).

### Table 5.1: Time spent preparing application (hours)

<table>
<thead>
<tr>
<th></th>
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<th>Firm (147)</th>
<th>Successful (76)</th>
<th>Unsuccessful (131)</th>
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<td><strong>EOI / Outline stage</strong></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
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<td>74</td>
<td>98</td>
<td>99</td>
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</tr>
<tr>
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<td>53</td>
<td>65</td>
<td>59</td>
<td>61</td>
</tr>
<tr>
<td><strong>Full stage application</strong></td>
<td></td>
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<tr>
<td>Lead Applicant</td>
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</tr>
<tr>
<td>Colleagues</td>
<td>129</td>
<td>80</td>
<td>86</td>
<td>98</td>
<td>94</td>
</tr>
</tbody>
</table>

Source: Survey of applicants, effective sample size in brackets.

### Table 5.2: Time spent preparing for MAC interview (hours)

<table>
<thead>
<tr>
<th></th>
<th>Academic (10)</th>
<th>Firm (103)</th>
<th>Successful (58)</th>
<th>Unsuccessful (55)</th>
<th>All (113)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time of lead preparing for MAC</td>
<td>67</td>
<td>43</td>
<td>31</td>
<td>61</td>
<td>50</td>
</tr>
</tbody>
</table>

Source: Survey of applicants

However, these costs reflect only the time spent by the lead applicant. As illustrated in figure 5.6, approximately half of all applicants worked with another party to prepare their bids, implying that these estimates understate the costs involved in preparing applications. In general, it appears that successful applicants were less likely than unsuccessful applicants to have worked collaboratively on an application.

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34 Annual Survey of Hours and Earnings, Office for National Statistics, 2014
Figure 5.6: Percentage of applicants working with other organisations to prepare their applications

Source: Survey of Applicants, effective sample sizes included in brackets.

5.2.4 Benefits arising from preparing an application

Applicants identified a number of benefits arising from preparing their submissions. The process of applying to the Biomedical Catalyst was associated with giving additional scientific scrutiny to their projects, improving planning, or strengthening plans for exploitation for more than half of all applicants. These effects were identified in a selection of the case studies where one applicant in particular felt that the pressure of preparing an application drew in attention and additional scrutiny on the idea of the project from across their research group, the university technology transfer office and their academic partner. The questions on market need were seen as particularly valuable by applicants. As anticipated, this effect was generally strongest among successful applicants. A greater share of academic applicants identified these benefits in comparison to those from firms.
Biomedical Catalyst Evaluation: Process Evaluation and Baseline Impact Evaluation

Figure 5.7: Percentage of applicants who agreed with the statement that the process of applying to the Biomedical Catalyst had helped to...

Source: Survey of Applicants, average effective sample sizes included in brackets. Note: either tended to agree or strongly agree

5.3 Assessment or Review Process

As noted above, the policy objectives of the Biomedical Catalyst are to support the pull-through of academic research into the commercial sector and the growth of the life sciences sector by responding to market failures associated with the commercialisation of intellectual property. Overall it appears that the criteria under which projects are assessed and reviewed fits well with this objective. The focus and scrutiny given to the science involved with applications is incredibly high, offering confidence about the ability of the scheme to support only high-quality scientific opportunities. However, the extent to which the process focuses on the commercial aspects of projects, and extent to which it effectively targets market failures by supporting ‘additional’ projects is less clear.

5.3.1 Quality of information received from applicants

There was some divergence in views on the quality and usefulness of application forms across the different aspects of the programme:

- **Medical Research Council**: A large volume of information and material was received to support each submission from academic applicants. Application forms are typically 90 pages in length and are highly detailed. In general the quality of this information was very highly regarded by stakeholders involved in project selection. The quality of the description of science was seen as particularly strong, offering a very high quality evidence base on which to make decisions. It was felt that information about the commercial potential and business case was consistently present for applications, but was less fully articulated than scientific details. In some cases it may have been difficult to assess the commercial viability of applicant projects or their potential to secure further private or public follow on funding should the project prove successful. From a review of the
application forms for case studies, and drawing on stakeholder views, the quality of information available from applicants on the add-on (the extent to which public funding would be additional to private sources in responding to market failure issues) of their projects was less strong than the scientific or commercial potential. Here, arguments generally related to the reluctance of the private sector to fund translation research. One applicant suggested that they would have been happy to include more detail in this area within their application in the form of a return on investment calculation.

- **Innovate UK**: Stakeholders identified a generally lower level of satisfaction with the quality of information received from industry applicants when considering both the original application forms, and the responses to follow up questions identified by assessors. Panel members in particular felt that the information submitted in industry-led applications was insufficient to enable them to make a funding decision. There was a concern that text describing the projects was too focused on commercial and business-planning issues to be informative about the content of the project. However, the key gap identified by stakeholders was around the depth and quality offered in the application forms about the science behind the projects to be pursued. It was felt that there was often not enough detail to assess the claims of novel understandings and approaches being made in many applications. It appears that panel members frequently used internet searches and review of academic journals to supplement the information provided. This not only implies that there may be significant gaps, but since the research occasionally identified different results, it undermines the confidence in the quality of the evidence submitted by applicants. Several stakeholders suggested that the forms should have better prioritised the science, with less attention given at submission to project management and exploitation plans, although there was no consensus here. Others suggested that more space was needed to discuss the science in greater depth.

As noted above, the Innovate UK application forms were expanded in length before round 4. This appears to have been a well-received change by those applicants who were aware of it. There may be scope for further extending the application to include a scientific appendix without creating an undue burden on applicants. This could draw on a Medical Research Council template which allows the applicant to submit annexes in the following five areas:

1. Extra detail on ethical, risk or patient safety data issues
2. NHS Trust contribution information, as outlined in the section below on full trial grants
3. Project Partners' letters of support and
4. Limited additional annexes may be allowed in exceptional circumstances for proposals addressing large population studies, including clinical trials.
5. For requests for follow-on funding MRC includes the most recent quarterly or milestones report for the precursor project in in the application.

It is important to note that this was not a unanimous view of stakeholders. Some felt that the forms provided enough information, and a consulted panel member\textsuperscript{35} felt that it was too much information for a panel to efficiently review. It was suggested that adding an executive summary to the application form would bring the application together and enable a more rapid review of the application. The suggestion was that applicants would be constrained to one side to describe:

\textsuperscript{35} In total the evaluation included 30 stakeholder consultations, programme secretariat and MOs (10), assessors (2) * Peer reviewers not covered, CiC, DPFS, and MAC (4), member organisations, investment community and investors (11), wider Policy (3)
Biomedical Catalyst Evaluation: Process Evaluation and Baseline Impact Evaluation

- The problem
- How they plan to solve it
- How others are trying / do the same thing
- Costs needed to do it
- Economics of the idea in the future

Confidence-in-Concept: CIC applications submitted in the first year of funding were relatively short 8 page application forms which in the third year of funding turned into more substantive documents, with project portfolio analysis and listing of the descriptions of all funded projects. The quality of information submitted is to some extent a direct result of the clarity of monitoring requirements relating to this stream of funding. Case studies revealed that there could have been clearer guidance here as the KPIs were not provided and therefore the characteristics by which the HEIs are monitoring their projects vary. In some instances the CiC panel expressed their dissatisfaction with the level of detail in the CiC application forms, at times to the point where the brevity of the summary of previously funded projects made it very difficult to assess the suitability of project selection or the success of the subsequent work.

5.3.2 Reviewer and Assessor Expertise

A number of applicants expressed particular concern that poor quality feedback\(^{36}\) received on their bids suggested that those appraising bids did not have sufficient expertise to do so reliably. Through stakeholder interviews this was identified to be a particular issue for firm applicants and assessor review.

Innovate UK assessors are drawn from a pool of approximately 200 contracted individuals. The Lead Technologist is responsible for identifying suitable assessors for each application. This is done on the basis of their personal knowledge of the assessors and a response to a survey where they indicated their particular areas of expertise. Assessors are paid a small fee\(^{37}\) for each application that they review. The concern identified by applicants was that feedback was highly ‘variable’. The comments and feedback from some assessments were said to demonstrate a very strong understanding of the topic areas of the application (something that fitted well with the very highly experienced Innovate UK assessors that the study team spoke with). However, other assessments were found to be severely lacking, and it was suggested that assessors sometimes failed to understand the content of the application.

MAC panel members expressed concerns over the level of experience of some of the Innovate UK assessors. They suggested that many were not demonstrating a high level of scientific understanding of the content of the application. It was suggested that much of the feedback offered was ‘unhelpful’, such as a one sentence “this is a brilliant project”. Panel members also offered examples of projects, which in their opinion should not have been recommended and taken to the MAC, and which were seen as an inefficient use of time of this precious resource. They identified instances where a claim of ‘novel science’ made by an applicant was taken at face value by an assessor, but through a quick internet search was found to have already been demonstrated by others several years previously. This is not a shortcoming of the Innovate UK assessment panel instrument as such but it demonstrates the need for it to be supplemented by a strong scientifically rigorous panel as the MAC.

While there was general satisfaction with the ability of assessors to review business plans, and identify strong commercial opportunities, issues were identified in two areas:

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\(^{36}\) Please note that the role of feedback is explored in greater depth in Section 5.4 below.

\(^{37}\) Collaborative R&D expression of interest and a feasibility stage £100 per application, and £150 for a Full Stage Collaborative R&D
• **Concern over the limited pool of assessors available to comment on applications** – it was felt by some stakeholders that it might be difficult for a finite group of individuals (which grew over the life of the programme) to cover such a broad range of areas or to offer sufficient depth to review multiple applications in similar areas. This comparison was made in relation to the peer review process that draws on a global research community. This was felt to be driving the issues with variable quality of assessment provided by Innovate UK assessors indicated by the lower correlation with panel scores.

• **Concern about the way in which feedback is given.** Assessors are asked to respond to a series of specific questions and to score the application. A small number of stakeholders expressed concern that this stop-start approach might be easier to complete with limited knowledge of the topic, than if assessors were required to comment on applications in narrative form (in a peer review fashion).

Analysis of the applicant survey (figure 5.8) identifies a group of dissatisfied applicants from both academic and firm backgrounds. The fact that these are heavily concentrated amongst unsuccessful applicants suggests that an element of the issue may relate to the rejection of their application. However, it would be unrealistic to expect successful applicants to question the expertise of individuals who had clearly agreed with them, so it is important not to dismiss this evidence.

**Figure 5.8: Percentage of applicants who felt satisfied with the clarity with which the reasons for the funding decision were communicated**

Source: Survey of Applicants, effective sample sizes included in brackets.

The levels of dissatisfaction identified in figure 5.8 above among academic applicants are surprising, since the qualitative research (stakeholder and case study interviews) identified a very high level of confidence in the reviewers used by the Medical Research Council, a process one stakeholder described as ‘flawless’.

The Medical Research Council review process involves two rounds of assessment. The outline applications undergo assessment by the DPFS panel. In the full application stage the application is subject to a peer review. Applicants can nominate up to 3 independent reviewers whom the Medical Research Council may approach for assessment of the research proposal. When a full application is received, an external selector is appointed to
identify a number of experts (always including a relevant statistician) to review the application (if they fail to secure enough individuals, programme managers will supplement this list). Selectors are free to recommend any suitable individuals and are not limited to UK individuals or a set pool of experts. A platform is used to check for conflicts of interest and then approach these individuals, secure their consent and then allow them two weeks to review an application. Reviewers are then asked to offer their feedback as a single narrative. Stakeholders felt that this offered very high quality scrutiny of science.

5.3.3 Guidance Provided to Appraisers and Reviewers

Innovate UK assessors are provided with a guidance document outlining the remit of the process and detailing each of the 6 questions on which they give their view when scoring the proposal. The document ends with a description of the ‘recommendation for funding’. Innovate UK also regularly holds a webinar for assessors to ensure that they understand their roles and responsibilities. One of the assessors who has been consulted stated that the webinar is probably useful for the less experienced assessors but not for those who have been involved in this process for years.

Due to issues of confidentiality it was not possible for the study team to interview any Medical Research Council reviewers (their role as well as which projects they review is held in confidence). However, Innovate UK assessors expressed satisfaction with the guidance that they had received.

There is currently no process of development in place for assessors or reviewers. Assessor workshops were run in the early rounds of the programme, but have not been repeated recently. Assessors commented that they work in isolation and never learn the extent to which their comments are in line with what others have written (especially important for benchmarking their own scores). Assessors, for example, only meet to discuss an application when there is a particularly wide variation in responses. Some form of regular catch-up or training for assessors could be helpful, and would be feasible given the size of the pool. It was suggested that this is used on other projects such as Smart. This might be more difficult to achieve in practice for Medical Research Council reviewers. However, perhaps a core of the most frequently used reviewers could be supported in this way. Panel members expressed displeasure that they had not had the opportunity to feed into the development of the guidance for either Medical Research Council reviewers or Innovate UK assessors. It appears that there would be appetite from this group to be involved with delivering any training.

5.3.4 Focus on Additionality

Project stakeholders and panel members demonstrated a clear understanding of the issues associated with assessing additionality when speaking with members of the evaluation team. Guidance for Innovate UK assessors identifies a clear focus on this aspect and notes that for projects receiving a top score “there is a very strong explanation as to why the project would not happen without public funding”. Assessors stressed that this was something that they were searching for when looking at projects.

The MRC Reviewer’s Handbook\(^{38}\) mentions return on investment as one of the criteria for excellence. Here a high return on investment is assessed in terms of the resources requested, the likelihood of delivery of anticipated project results and the expected knowledge generation rather than from a commercial or financial return on investment perspective. However, relevant stakeholders stressed that the review process focuses on medical need and scientific rigour much more strongly than its ability to identify potentially additional projects. It was instead suggested that the design of the Medical Research Council application process (its focus on early stage

\(^{38}\) http://www.mrc.ac.uk/documents/pdf/reviewers-handbook/
projects far from market and the long lead times involved) would be key for deterring any applicants who could have more quickly accessed private funding.

5.3.5 Level of Resources Available for the Assessment and Review Process

The evaluation identified no evidence that a shortage of resources is negatively impacting on the assessment and review process. The Medical Research Council secretariat appears to have a highly effective IT platform to manage the assessment and review process. Their ability to call on leading experts (both from within and outside of the UK) to review applications on a pro-bono basis is a major advantage, and makes the process highly resource efficient.

At Innovate UK a key crunch point appears to be the rapid turnaround time between receiving applications and passing them on to assessors. This was previously handled by one Lead Technologist working alone, but the capacity in the team has recently been expanded significantly. Assessors have two weeks to review application and receive a small fee for each application they review. Two weeks was thought to be adequate and no issues were raised about this timeline. There was no suggestion during our stakeholder interviews that the compensation for assessors was too low, though in the consultants’ experience this does appear to be very modest. Additional resources would be required to manage the assessor pool if it were significantly expanded.

5.4 Project Selection Process

Following peer review (academic bids) or assessor scrutiny (SME bids) there are four routes forwards for applications:

1. Feasibility Study - Applications to Innovate UK Feasibility Studies do not go to the MAC and were selected based on a line draw based on the assessor scores.

2. Firm route to MAC - Early Stage and Late Stage applications to Innovate UK that pass the assessment stage, all give a 10 minute presentation of their application to the MAC and take questions after the session. Innovate UK’s MAC follows a ten point scale with the same three attributes (quality, impact and productivity) formally acknowledged in the guidance document. After three rounds, a specific MAC was set up to assess the applications that focus on medical devices and diagnostic tools as it is felt that they require a different range of panel expertise. All of the MACs consist of scientists and clinicians from business and academic sectors as well as representatives of the VC community who can together assess the science and business proposition presented.

3. DPFS - The applications to the Medical Research Council receive a review by the DPFS panel in the outline stage, in which two panel members present the application and give their view on its strengths and weaknesses. This is followed, at full stage, by a panel-wide discussion and scoring. Medical Research Council’s DPFS panel uses the same ten point scoring system as the MAC, from 1 – Unacceptable quality or serious ethical issues through to 10 – Exceptional – Top international programme or of exceptional national strategic importance. The attributes that the panel looks for are quality, impact and productivity, each of them defined under a number of bullet points in the scoring guidance document.

39 Collaborative R&D expression of interest and a feasibility stage £100 per application, and £150 for a Full Stage Collaborative R&D

40 Initially the Early Stage award assessment was done using an internal ‘Moderators panel’ involving the normal assessor pool and only Late Stage awards went to the Major Awards Committee. After initial two rounds, the MAC was concerned that the Early Stage awards should also go through this process, especially as some of them were of substantial value.
4. Academic route to MAC. The academic applications furthest along the development pathway and closest to commercialisation are routed to the MAC rather than the DPFS panel.

It is worth noting that appeals to panel decisions or responses to final feedback are not an option; however, both Innovate UK and the MRC actively encourages resubmissions and the MRC can waive its one-year resubmission rule where appropriate.

5.4.1 Strategic Alignment

The overall policy objectives of the Biomedical Catalyst are to support the pull-through of academic research into the commercial sector and the growth of the life sciences sector by responding to market failures associated with the commercialisation of academic IP.

Pull through of academic research

While not specifically mentioned in the panel scoring guidance document, the DPFS panel members focus on the soundness of the science and the approach towards addressing a medical need. The MAC panels (therapeutics, and diagnostics and medical devices) have a stronger focus on the business proposition while trying to understand the innovativeness in the science behind it and the appropriateness of the team to deliver the project. Both MAC and DPFS panels consist of highly regarded scientists and have a broad coverage of fields relevant to life sciences. They are therefore well placed to judge the scientific quality of the applications to ensure the pull through of the most promising academic research possible. The previous section identified issues surrounding the assessment process. Limitations on information and the application forms for SMEs impact on the ability to select the most scientifically sound proposals and therefore influence the pull through of academic research. These shortcomings which were identified by a number of stakeholders are more significant for Feasibility Studies which do not undergo the scrutiny by the MAC panel.

Several stakeholders identified a concern that the focus of the selection panels on the ability of applicants to demonstrate the science they plan to exploit may come at the cost of support for some highly innovative and exciting opportunities. Applications were not only assessed based on the quality of scientific ideas, but also the extent to which they had been tested and were therefore likely to yield the further results that investigators were hoping for. It was suggested that this approach might make the selection process ‘risk averse’ and potentially result in projects with high potential which might ‘knock it out of the park’ not proceeding (though it should be noted that the use of monitoring milestones by the MRC helps mitigate risks). It does appear that the risks and potential rewards associated with a project are not compared (or at least not quantified for all) during the selection process. This focus on the projects where the science has already received a great deal of attention may to some extent be a function of the high volume of applications received by the panel and their ability to therefore be highly selective.

The DPFS had a very strong focus on the pull through of academic research but less of a focus on commercial value of such academic outputs that were associated with the activity. The potential for the growth of the sector to be supported was investigated less strongly than by the MAC. The DPFS examined pathways to impact rather than a business plan which may offer less direct interrogation of the commercial opportunity. Some evidence from the case studies suggests that in a number of cases the potential routes through to economic value creation of funded project was highly uncertain at the time of application. This might be expected in the earlier stages of product development, especially in case of academic research.
Supporting the growth of the sector by responding to market failures

The MAC has a high representation of the VC sector and therefore has a strong ability to assess commercial rationale and understanding of the applicants of the developmental pathway that the product/tool would need to take to be successfully commercialised. There was no evidence of a systematic approach to attain consistency in decision-making between and within rounds. There was a general consensus among consulted stakeholders that the panels made their decisions to fund the best projects based on sound science and with strong business propositions. The set of questions that were discussed prior to applicants entering the room and the attributes of the application that were questioned varied project by project. The MAC was nevertheless universally seen as a strong tool that would make up for any shortcomings in the previous assessment stages (outlined in previous section) and would see through any relationships between the project team. Some unsuccessful applicants nevertheless disagreed with the decisions of the MAC and criticised its ability to identify high quality projects. Some went as far as to describe the ‘rapid-fire’ nature of questioning at the sessions as a ‘raffle’. It was generally thought by internal stakeholders to the programme that if the MAC did not highlight a problem with the application, there wasn’t a problem.

Additionality was seen as an attribute that is difficult to judge by both the assessors and panel members, especially for the ‘Early Stage project’ proposals. Observation of DPFS and MAC panels also suggested that additionality was given less attention than the science behind projects. The fact that a number of successful academic applicants contacted as part of the programme found it difficult to articulate a clear route to market for their projects suggests that these economic issues were not investigated to the same extent as points of science. One panel chair confirmed this by expressing the view that identifying additional projects was his priority, but he was unsure the extent to which all panel members have it on their mind during meetings.

The practical mechanisms and routes through which additionality is assessed as part of project selection is also not clear. While several stakeholders and panel members demonstrated a clear understanding of the issues, they were less clear on how to test for it when deciding about projects. Several stakeholders were of the opinion that additionality is a difficult thing to assess or for which to develop questions to provide a basis for a robust test. There were also differing opinions amongst those that felt it could be readily assessed. For example, there was an apparent tension between interviewees who suggested that the programme should in effect operate as a ‘funder of last resort’, only backing projects which cannot secure alternative funding, and those who felt that private investment was a good indicator of project quality and that the willingness of others to invest should be reflected in project selection (though clearly such an approach would raise concerns that public spending would crowd out private investment in such cases).

Several stakeholders and applicants suggested that the programme had been designed for the capital market conditions of 2011 where funding was so constrained that displacing private investment was unlikely to be a risk. They suggested that as the capital market recovered (discussed further in section 3) potential issues of additionality would become more significant. When asked to look to the future of the scheme, a number of stakeholders and applicants suggested that it would be important to place greater emphasis in this area. Suggestions for achieving this included the programme secretariat being encouraged to focus more on earlier stage, higher risk projects, establishing clear benchmarks for what types of projects can be expected to access private funding, or specifically requesting applicants to explain in greater depth why they are unable to secure private investment. Applicants consulted within the case studies highlighted that answering what would have happened without the funding is extremely difficult to judge but agreed that it is important to do so to justify public funding.
The MAC panel members reported that they to some extent ‘learnt on the job’ which resulted in a somewhat limited understanding of goals and objectives among some of them, especially in the earlier rounds. As a result, in the initial rounds when the panel members were not confident about the goals, they may have exerted higher levels of risk aversion, i.e. the applications that were funded represented those with more developed methods based on solid pilot data proving certain level of efficacy of the treatments proposed.

One of the internal stakeholders to the programme identified a potential criticism of the assessment and project selection process in that it is sequential and assesses separately the technology, the need and the route to market in a series of questions. It is therefore not assessing the extent to which this proposition is the best way forwards to address the need, but the extent to which this approach might work.

There were some indications from unsuccessful applicants that at times they felt that the MAC did not always have the necessary skills to judge the variety of applications, especially when the proposal received high scores by the assessors and then failed to pass the MAC. The addition of a MAC for medical devices has to some extent addressed the skillset coverage; however, some concerns about the inconsistency in decisions of MAC and the recommendations of the assessors remained. All internal stakeholders were highly complementary of the process for selecting projects as a highly rigorous one, steered by highly respected individuals in their scientific fields.

The chairs of both the DPFS and MAC panels were highly engaged and demonstrated excellent skills in leading a group of top individuals in their respective fields. During the observed sessions the DPFS panel members presenting the applications demonstrated an admirable grasp of the concepts described in the proposals. The DPFS panel does not have the privilege of interrogating the applicants and therefore must rely more heavily on information provided. The application forms submitted to the Medical Research Council are generally in excess of 80 pages long and the systematically selected peer reviewers, each giving a qualitative assessment of the quality of the proposals, gives the panel members higher levels of confidence than those exhibited by the MAC panel members towards the independent assessments of Innovate UK applications.

A recent independent audit of the Biomedical Catalyst undertaken for the Medical Research Council by the Audit and Assurance Services Group highlighted that Medical Research Council guidance material for applicants includes detailed criteria against which their applications should be assessed. However, these criteria are not used directly by individual panel members in assessing applications. The audit therefore recommended that there should be a direct link between the Biomedical Catalyst outline/EOI and full application assessment guidance criteria and the criteria used by panel members in project selection. This recommendation is in line with our findings and would enhance consistency between the two processes (the extent of this problem is described in section 5.2).

5.4.2 Time Available for panel Members

The DPFS is a panel with over 20 members covering a breadth of relevant scientific fields. Drawing on interviews with panel members and direct observation, discussions at the panel meetings indicated that the panel members spent sufficient time and had enough information to make informed decisions on project selection. More extensive application forms and carefully selected peer reviewers induce trust in the system and resulted in general satisfaction with the level of information available and time received to review the applications. This strongly suggests that the panel had allocated sufficient time for reviewing applications.

The MAC panel members receive only one paid day to review the applications. This time is seen as inadequate by some of the panel members, given the quantity of information in the application forms and the variability of the quality of external assessments (explored above). The MAC runs to a strict schedule for review of each application incorporating a 10 minute presentation followed by a 20 minute interview. Stakeholders suggested that
in a minority of cases this tight timeline does not allow the opportunity to cover all of the points felt to require clarification by the panel. Some applicants expressed concern about this short time window, particularly as they were concerned that material provided previously had not been reviewed by panel members. One applicant detailed that “it just seemed as though you go into the MAC interview, everything’s forgotten, and you’ve half an hour to try to convince these ten or 12 people that they need to fund your project, kind of from scratch, like Dragon’s Den”. It was noted that occasionally one of the chairs will overrule this time limit and ask one last question but generally the schedule is strictly adhered to.

5.4.3 Feedback to Applicants during Project Selection

Both Innovate UK and the Medical Research Council invest heavily to ensure applicants receive constructive feedback at several points in their application. All consulted parties confirmed that feedback was a central part of the Biomedical Catalyst programme; some saw it as a necessary attribute for developing a sector rather than just funding it.

For applications which are passed to the Medical Research Council strand of the programme, the outline applications receive detailed and specific feedback on which parts require improvement and in some cases, also, specific additional questions to answer. The Medical Research Council holds an applicant workshop for all successful applicants from the outline stage to improve the quality of full stage applications. This workshop was very well received by most case study applicants. Most had found it a helpful forum in which to receive detailed and tailored feedback and to gain an understanding of how to refine their bids. One applicant did however comment that, while they felt the session would have helped less experienced researchers entering the field of translational research, the session was not well tuned for someone with his high level of personal experience.

Innovate UK and MRC share with applicants their individual assessor or peer reviewer comments prior to attending the MAC (offering a chance to respond to comments prior to interview at MAC). Detailed MAC feedback dictated by the chair is also passed onto applicants.

The applicant survey suggests that, in general, feedback at the EOI/outline stage is well received:

- Similar proportions of applicants agreed and disagreed with the statement that feedback resulted in adjustments to the objectives of the research project (42 per cent agreed with the statement and 47 per cent disagreed). Successful applicants were slightly more likely to agree with that statement. Academics were more likely to strongly agree with the statement than firms.
- A slightly higher proportion of applicants agreed than disagreed with the statement that feedback resulted in adjustments to the design or planning of project e.g. of clinical trials (52 per cent agreed with the statement and 38 per cent disagreed).
- Similar proportions of applicants agreed and disagreed with the statement that feedback resulted in adjustments to the costs associated with the project (44 per cent agreed with the statement and 41 per cent disagreed). Successful applicants were slightly more likely to agree with that statement. Academics were more likely to strongly agree with the statement than firms.
- Similar proportions of applicants agreed and disagreed with the statement that feedback resulted in improvements to the exploitation plan (46 per cent agreed with the statement and 41 per cent disagreed). Successful applicants were slightly more likely to strongly agree with that statement. Firms were significantly more likely to agree with the statement than the academic applicants.

Qualitative evidence from case study interviews indicates that there could be greater transparency in the outline stage feedback with respect to the decision about which applications to the Medical Research Council will need
to present to the MAC. This would entail detailing the specific attributes of the projects that resulted in this different assessment route for the proposal. The study team has also collected some very positive evidence in our case study interviews where the applicants were able to point out examples of how they benefited from clear information on declined outline bids. Applicants suggested that feedback had helped them to refine and develop their bids – regardless of the success of the application. One ultimately successful applicant in particular had received a negative response to their original outline bid, but very much appreciated the clear instructions that they should make changes and then re-submit their application. This was seen as a much clearer approach than that used by other schemes such as EU funding. Furthermore, panel members felt able to identify examples of applicants significantly improving their bids in response to feedback.

Satisfaction with feedback was more mixed at the full application stage. Overall half of the respondents were fairly or very satisfied with regards to the clarity with which the reasons for the funding decisions were communicated, five per cent were neither satisfied nor dissatisfied and 45 per cent were fairly or very dissatisfied. As one would expect, the satisfaction amongst successful applicants was very high (90 per cent of successful applicants responding to the survey stated that they were fairly or very satisfied with the clarity of communication) while unsuccessful applicants were much less satisfied with the clarity of communication (67 per cent of unsuccessful applicants responding to the survey stated that they were fairly or very dissatisfied with the clarity of communication).

Figure 5.9: Thinking about your overall experience of the Biomedical Catalyst application process, how satisfied or dissatisfied were you with...
Figure 5.10: Thinking about the formal feedback you received after the EOI/outline application, how far do you agree or disagree this led to any changes in the design of your project in terms of...

A number of issues were raised with respect to feedback from Innovate UK (generated from the comments of independent assessors). Concerns were raised by stakeholders about the extent to which this was specific about the methodology and that it was less substantial that that provided by the Medical Research Council. As noted above, a number of applicants suggested that feedback was of ‘variable’ quality. Some stakeholders voiced their opinion about the need to improve the consistency of the feedback provided to firms. The survey results point towards varying views on the quality of feedback received from Innovate UK (addressed in 5.3.2). Some applicants indicated that the feedback could be further improved by offering more guidance on possible exit strategies. However, it was recognised that this could exacerbate issues around conflicts of interest. There were a number of suggestions from consulted stakeholders on how feedback could be improved. One relates to the point mentioned above to change in its structure – i.e. to a narrative form. A second suggestion was to ask assessors to respond only to questions they feel fully qualified to comment on, leaving other areas blank. Finally, it was felt that additional quality checks and feedback loops could improve consistency and quality. This would involve some additional opportunities to share knowledge between assessors.

In the full stage application process and throughout, the evaluation found that the feedback given by the Medical Research Council is very thorough and many times goes into the detail of the proposed method. It was felt by applicants that there is an attempt to be constructive to ensure that the best applications are received and that the iterations allow for further improvement. This is substantiated by the higher satisfaction expressed levels by the academic applicants described above.

One possible explanation for the higher levels of satisfaction expressed by academics is the flexibility and feedback offered by the Medical Research Council. The Medical Research Council incorporated flexibility into the application process and allowed for successful outline applicants to skip a round in the full application in order to...
give more time to applicants wishing to make substantial improvements to their bids. This two stage process allows the Medical Research Council to track the improvement in applications between outline and full submission. All internal stakeholders had a perception that the feedback given to the applicants is of great importance. This was confirmed through case study evidence as stakeholders suggested that they had been able to track responses to comments and feedback strengthening applications through the processes (e.g. from outline to full bid for the Medical Research Council). Some unsuccessful applicants however expressed the view that they would wish to be able to respond to the decision of the panel. However, both Innovate UK and the MRC actively encourage resubmissions and the MRC can waive its one year resubmission rule where appropriate.

5.4.4 Need to Defray Resources

The selection process does not appear to be driven by a need to defray resources, and no stakeholders were able to identify any indications that this has been the case throughout the lifetime of the programme. Instead of looking at the projects by budget per call, the decisions appear to be purely driven by quality of application. Under exceptional circumstances of receiving too many high quality bids there is a possibility of holding the best ones over to the next round, though the use of this process has only occurred once for the MRC and never for Innovate UK.

5.4.5 Time Taken to Make Decisions

An important disadvantage of the application process, however, appears to relate to the time taken from application to decision, especially for academic applicants. Qualitative interviews identified a high level of satisfaction with the rapid rate at which firm applicants receive a decision on their applications, typically six weeks. Stakeholders identified this as an important feature of the programme which should be protected going forwards. In contrast the long timelines associated with bids from academics were identified as a significant obstacle, typically 2-3 months. This view is supported by analysis of the applicant survey. A sub-set of academic applicants (approximately one third) identified themselves as either fairly or very dissatisfied with the time taken from application to decision. While this was more likely to be cited as an issue by unsuccessful applicants, 30 per cent of successful academic applicants expressed dissatisfaction here.
Figure 5.11: Percentage of applicants who felt satisfied with the time taken from application to decision

Source: Survey of Applicants, effective sample sizes included in brackets.

Figure 5.12 details the impact of these delays on applicants. They appear to be most significant in holding back activity on projects and risking a loss of staff working on projects. This matches the evidence gathered through case studies – for example, one academic applicant experienced a twelve month hiatus in the project while preparing an application, refining their submission following the rejection of their outline application and awaiting its result. While they felt that the project had improved as a result of the iterative feedback they had chosen to focus on other areas of work rather than this project during that time.
5.5  Contracting and Due Diligence

5.5.1  Due diligence and Timescales

Innovate UK applies standard due diligence checks on all successful firm applicants which are consistent with other Innovate UK run competitions ranging from small grants (e.g. Innovation Vouchers) through to multi-million pound, multi-year projects. Once the conditional offer letter is issued, each successful application undergoes a financial viability check (assessing the financial viability of each partner in the application). Checks include a review of the financial performance of the firms and their cash flows, confirmation of parent company or venture capital approval of the matched funding and internal management reports and external audits. Larger grants require more scrutiny because they will typically include more partners and items to be checked. Due diligence does not cover any validation of financial projections or assumptions in the proposals. Stakeholders saw the due diligence processes as largely adequate.

One issue highlighted was that more could be done to educate and prepare applicants prior to their meeting with the MAC. One panel member expressed concern that it would be difficult for due diligence processes to address the risk associated with foreign companies setting up UK subsidiaries purely to access Biomedical Catalyst funding without delivering any development activity in the UK. This was a risk which the stakeholder felt was most effectively managed through checks made on companies by MAC panel members.

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41 No comparable processes are adopted by the Medical Research Council.
Once financial viability checks are passed, the competitions team check eligible costs. These have strict qualification criteria that are closely examined. For example, only administrative overheads are covered not full absorption cost.

The time required for contracting and due diligence activities varies greatly. This depends on the availability of data and the level of collaboration from the applicant. There were instances in which the conditional offer was never made due to issues raised by the checks. A point of regular contention is the eligibility of overheads. Any points that require further discussion, such as whether the costs of materials are realistic, are raised with the Lead Technologist by the contracting team. Likewise, high levels of subcontracting will be questioned. This process on many occasions requires several rounds of discussion with applicants, some of which are face to face. A typical time from conditional offer letter for a standard Biomedical Catalyst application to final approval ranges from a few weeks to two months. Some substantial projects with larger consortia have taken much longer.

The majority of applicants (78%) agreed to some extent that the time required for due diligence before authorisation for a project to kick off was explained to them clearly. Evidence from case studies indicates that the process of contracting and due diligence could be smoother and that the number of iterations between the applicants and the due diligence team could be reduced. With respect to contracting, there were a number of occasions on which incorrect information was issued in conditional offer letters. One applicant understood that a common approach to due diligence was applied across the programmes and felt that the contracting and due diligence process for their Feasibility Study was too onerous for the size of the award.

5.5.2 Value of contracting processes

Stakeholder interviews with those involved in the Innovate UK contracting processes identified that the information generated from the contracting and due diligence stage does not directly result in a project plan which is used for monitoring project progress. Instead, firms must generate a project plan based on the application that is approved by the MAC. They are provided with assistance by the monitoring officer who if necessary sends the successful applicant a project plan template to help them. Applicant skill levels in project management were identified as a key issue by monitoring officers. This was identified as creating a particular issue because project management is not dealt with in a systematic fashion. The process of generating a grant offer letter relies heavily on the plans drafted by the applicants. Whilst these are confirmed and sense checked by the monitoring officers and liaison officers they are set and remain the responsibility of the firms.

In both the MRC and Innovate UK strands of the programme, DPFS panel and MAC conditional offers can be made requesting conditions added prior to project funding being confirmed. This occurs much more frequently in the MRC strand of the programme, where milestone alterations are also often requested. The grant award letters contain terms and conditions and the payments are made quarterly in arrears. However, one academic applicant did express concern that the contracting process had taken too long and involved too many iterations. They suggested that for their project, the process had tried to pin down too many elements of the programme before its inception – for example they found it difficult to specify all of the elements of animal models in advance.

42 Overheads proportional to the project are eligible. Applicant’s overhead rate is calculated as "Total Overhead Costs divided by (Total Payroll Costs less Administration/Support Staff Costs)". This percentage is then applied to labour costs incurred directly in the project.
43 i.e. overheads which are not proportional to the projects.
5.6 Delivery and Monitoring

5.6.1 Performance Management and Aggregated Performance Management

As with contracting arrangements, Innovate UK has standard monitoring processes in place across different Innovate UK programmes. Through these, applicants found that the monitoring officers were able to take a highly constructive and practical approach to contract management which goes back to the project plan drafted by the successful applicant and largely depends on their project management skills. Applicants found the monitoring officers showed a high level of flexibility in how they supported companies (by asking questions rather than giving advice – which they are not allowed to provide under Innovate UK rules). This was very much appreciated by the applicants. One case study applicant suggested that they found the inputs from the monitoring officer useful for the development of their programme of work and complimented the monitoring officer on good understanding of SME needs. Applicants consulted in the case studies were largely satisfied with the monitoring processes which one of them referred to as ‘light touch’. Monitoring processes were seen to positively impact on being able to keep applicants on track.

Representatives of Innovate UK felt there is sufficient information in the monitoring framework – both the timetable and milestones – to ensure that emerging issues with the delivery of projects are not missed. These representatives agreed that additional detail in the Grant Offer Letter (forming the contract) is not required. In case there are dependencies within a project (such as work packages that require outcomes from other activities before they can be completed) these are included.

There is aggregated data available on Innovate UK project progress by share of project resources used. It is also understood that there are standardised RAG rating of projects updated on quarterly basis. Issues are raised with the Lead Technologist who has flexibility to make small changes to project plans, but extended completion dates were rare (and relative to the project – Feasibility Studies would not generally be extended by more than a couple of months and drug development projects might have been extended by up to 12 months if good reasons were provided) and the Lead Technologist cannot authorise any increases in awards.

Medical Research Council monitoring processes are standardised across all monitoring officers and rounds of Biomedical Catalyst funding. Each project issues quarterly reports which are reviewed in an MRC team meeting between monitoring officers. At the meetings, specific deliverables and milestones are discussed and serve as hurdles to be overcome before further funding can be released. These milestones are developed based on strong scientific justifications – for example if a milestone of crossing a blood brain barrier is not achieved, the project will close and only funding up to that point is paid out. There are instances when the panel members request a clarification of milestones or an introduction of additional milestones when approving a project.

This milestone-driven process is executed by a structured hierarchy of clearly defined roles, a system which is well set up to identify issues early and wherein requests for project alterations can be made. These are signed-off by the head of translational research, the chair of DPFS panel or the whole panel depending on the extent of the request. The performance management system at the Medical Research Council uses a RAG rating at milestone level which allows for early identification of issues but requires a good level of understanding of what the research team is attempting to achieve. The system allows withdrawal of funding to projects facing problems. The aggregated performance management system allows for easy identification of reasons for termination and phasing out of individual projects.

Case study evidence from one applicant indicated that this system might have terminated projects very quickly if performance is below expectations. CiC awards did not initially have a specific monitoring arrangement and universities developed their own monitoring arrangements (e.g. monthly meetings) and KPIs (e.g. milestones and
final outputs and progress since project end). The third year of funding saw change in the application form structure which was expanded by the information on project portfolio (a list of projects funded in the first two years with an indication of the outcome).

5.6.2 Feedback from Delivery and Monitoring

There are some examples of changes that have been made to the programme that have been motivated by learning from experiences of prior rounds. Firstly, it was noted by stakeholders that there was a conscious effort to increase awareness of med-tech companies about the programme. Secondly, the numbers of diagnostic tools and medical device projects received in the first two rounds of funding and their different nature appears to have led to the establishment of a specific MAC. Finally, the substantial size of several Early Stage awards in initial rounds led to change in process that included the scrutiny of these awards in MAC interview rounds.

5.7 Partnership Working

Innovate UK and the Medical Research Council have demonstrated a strong working relationship across a number of seniority levels (Programme Manager/Lead Technologist, head of translational research as well as chief executive levels). The working partnership and all collaborative efforts on the ground as well as on directorate levels have to be complimented as all the individuals involved are highly engaged and dedicated towards the success of the programme and its support of the best possible projects. The evaluation team was on many occasions impressed by the efforts from both sides for the benefit of the programme and with the final goal of funding projects that will make a difference and result in technologies improving the health and wellbeing of the nation.

The recent independent audit of the Biomedical Catalyst (noted in 5.4.1) supports this view. It found that the scheme helps put into practice Medical Research Council and Innovate UK partnership in encouraging and supporting biomedical activity across the ‘valley of death’. The Medical Research Council has effectively harnessed existing processes and developed these to help ensure the scheme is set to foster investment and achieve success. The audit found that there is regular exchange of management information between the Medical Research Council and Innovate UK on the scheme. While this is the case for awards, the level of information held in a presentable and analysable manner at application level by the Medical Research Council is much greater than that held by Innovate UK.

The independent audit also highlighted that the panels are provided with regular updates on applications submitted and awarded under the scheme. There are nevertheless opportunities for communication and awareness raising, as the evaluation has revealed that companies and investors are rarely aware of the MRC led strand of the programme, and that academics are rarely aware of the Innovate UK arm of the programme. Additional efforts in communicating the programme could be orchestrated to promote Biomedical Catalyst as one programme that serves SMEs as lead applicants and as collaborators and academics as lead applicants and collaborators, highlighting the benefits of each role. It is acknowledged that there are interactions between applicants and panel members (from academia and business) at the panel meetings and that the applicants recognised the value of this.

5.8 Supporting University-Industry Collaboration

As noted above, an overarching aspiration of the Biomedical Catalyst is to respond to a perceived weakness in collaboration between academics and those in business. This section considers the extent to which the programme has been set up to respond to this goal.
The programme has put in place limited formal processes to encourage the formation of new university-business collaborations. A process has been established through which commercial applicants with academic collaborators can receive full funding for the academics' component of the project. This funding covers 80 per cent of the ‘full economic cost’ of a project, reflecting a research council convention that the remaining 20 per cent will be provided by the institution. This has been well received by applicants. One applicant noted to the study team that because of this feature they had selected to work with an academic rather than a CRO. In one sense this can be seen as a positive collaboration outcome but it is not clear the extent to which this collaboration would have relied on a sharing of knowledge and experience as opposed to a more transactional relationship. Another applicant had used the scheme to increase the size of their overall award given that their privately funded internal project contribution was fixed. There is currently not an equivalent scheme through which lead academic applicants can secure funding for their commercial partners and the MICA framework is in place to ensure that Medical Research Council support meets their funding rules and does not break state aid regulations.

In more general terms however, the design of the programme is supportive of collaboration between those in academia and industry. As detailed throughout this section, the programme has been designed to select and support projects with the strongest scientific understanding of the specific opportunity and the clearest possible articulation of a plan to pursue that opportunity. Drawing on the applicant case studies it is clear that this is encouraging applicants to search out and bring together the strongest teams that they can to apply to the Biomedical Catalyst, regardless of the mix of academic and commercial applicants. The case study research identified examples of academic applicants working with firms to access key engineering strengths or firms working with academics to draw on the clinical experience of a particular academic (this is discussed in greater depth in section 6).

The idea of additional measures to encourage greater university-industry collaboration within the application process was discussed with stakeholders. It was strongly suggested that any requirements on applicants to bring together university and commercial partners could be detrimental to the quality of the programme. Applicants also stressed the importance of being able to submit an application to the Biomedical Catalyst with a focused team, drawing comparisons with European Framework programmes where multiple commercial partners are typically required.

In spite of this concern an opportunity to better support university-industry collaboration within the programme was identified through the course of the research by improving the way in which the Medical Research Council and Innovate UK strands of the programme are marketed together. Industry and academia have very different motivations for applying to the Biomedical Catalyst projects and the programme would benefit from clearly communicating what the benefits are from being a lead or a partner in an industry-led and academic-led project. For example an SME might want to be a collaborator in an academic-led project if it is a project that lies on the periphery of its business or is built around the academic's idea. The same SME may wish to choose to pursue an Innovate UK route for the Biomedical Catalyst funding with a research idea in its core business where it needs to retain full ownership of the process. At the same time, the academics consulted within the evaluation valued collaborative arrangements as they went beyond standard purchasing of research or materials necessary to undertake the testing.

5.9 Summary

The programme has been well communicated. The Medical Research Council built on an existing programme and established communication channels with all universities involved its other translational research activities. Innovate UK communicated with subsets of the Biomedical Catalyst’s relevant sectors through a number of industry associations. There is however an opportunity to better develop and leverage the Biomedical Catalyst
brand and highlight the two distinct routes for industry and academic-led projects. In general the key target groups have a high awareness of the programme. But both the Medical Research Council and Innovate UK could have communicated these opportunities more effectively to some specific target groups (med-tech companies and universities without medical schools).

- There is a need for the Medical Research Council and Innovate UK to collaborate and develop a comprehensive marketing strategy for any future rounds of the programme. The design of this will need to target the full range of potential applicants.

- It would also be important for the Medical Research Council and Innovate UK to collaborate and build a single recognisable brand for the Biomedical Catalyst.

- This single brand could be used to help better explain the two routes to funding on offer from the Medical Research Council and Innovate UK respectively.

Applicants found the process of applying and submitting the application forms relatively straightforward, especially as both academic and industrial applicants were experienced in applying to public funding sources with similar requirements. Applicants felt that overall the process was asking the ‘right’ questions and encouraging a high quality of application. Information provided to the applicants about and throughout the process was viewed as clear and complete, though there were some signs that the route of the application process was more clearly laid out by Innovate UK.

- It may help to improve the quality of the assessment of applications from firms if the Innovate UK application form highlights the opportunity for applicants to include a scientific annex offering further detail on any science which they consider to be new and innovative within their application. Applicants contacted as part of the case study research displayed a lack of knowledge that they were permitted to include this type of information within one of three permitted appendices to a full stage application.

- Innovate UK could also help applicants to better prepare for the MAC by offering clearer guidance around what can be expected and the importance of being ready to respond to questions of a detailed clinical nature. The study team understand that additional guidance was offered to those invited to present to the MAC from round six onwards however majority of the few firms surveyed that attended MAC in round six were dissatisfied with the clarity of information on how to prepare for the panel.

The assessment processes are well set up by Innovate UK and the Medical Research Council but Innovate UK’s limited pool of assessors results in a perceived variability in the quality of the judgements made on applications. Feedback to applicants is seen as an important part of the process and both the Medical Research Council and Innovate UK make strong efforts to give constructive feedback to applicants in both stages of the two stage process. Medical Research Council’s feedback is more detailed and is associated with higher levels of satisfaction.

- There is an opportunity for Innovate UK to expand its current pool of registered assessors by approaching the global research community in this area to improve the depth and breadth of expertise that can be applied. This is a process that Innovate UK has started and the MRC is in a position to assist with this activity. Through a recent skills survey Innovate UK have been increasing the amount of knowledge it have about the detailed areas its assessors are qualified to comment on. This may help to improve matching and could help to ease this issue.
Changes in how Innovate UK assessors offer feedback, including a shift towards a more narrative style, and removing the expectation that all assessors should comment on applications from all perspectives could help to improve the perceived quality of feedback received. However, the study team recognise that Innovate UK assessment processes and IT infrastructure for the Biomedical Catalyst are universal to all competitions across Innovate UK (though other competitions do include additional stages such as a Moderation panel meeting). The implication is that achieving such changes may require a broad set of institutional approvals and investments.

Project selection is performed by panels made up of individuals who are highly regarded in their respective scientific fields and experienced venture capitalists who are well placed to judge the scientific and commercial potential of the projects. Panels scrutinise details behind the science and proposed method and the study team are confident in their technical ability to select the applications with highest potential for the pull through of academic research. Supporting the growth of the sector by responding to market failures is considered to some extent, but this appears to be a less prominent factor in the decision making process and there is little evidence of a systematic approach to attain consistency in decision-making between and within rounds. Concern was also expressed by a number of stakeholders that the expectations of the panel tested the science behind their ideas may have made the panel selection processes more risk averse than necessary.

- Guidance could be provided to panel members to more strongly and clearly focus their attention on issues of commercial impact and additionality.
- There is also scope to offer additional guidance to MAC members about what a good Biomedical Catalyst project looks like.
- For both MAC and DPFS panels there is also scope to ensure that the key question of ‘would this project be funded by other means?’ is at the forefront of member’s minds when scoring projects.
- In cases where the MAC feel that the science behind an application has not been adequately tested there is scope for the panel to have the option to recommend that Innovate UK offer the applicant a structured award when funding is initially released only up to the level of a feasibility award. Releasing the remainder of the award is contingent on the successful applicant using this feasibility award to address the issues identified by the MAC panel. This would only be appropriate in cases where the ideas for the project are seen as innovative, the commercial potential as strong and there is a clear reason why the project could not secure funding through an alternative route. Achieving this would be challenging within current Innovate UK funding systems as there is no route for pre-approval. An alternative approach, suggested by one stakeholder, would be to reduce the size of Early Stage awards and not require that they secure approval in the MAC. The acceptability of that approach would rely on an improved perception of the performance of Innovate UK assessors.

Both organisations, the Medical Research Council and Innovate UK, use standard contracting, due diligence and monitoring processes. The focus of Innovate UK on project management and monitoring relates to the applicants’ self-written project plans. The Medical Research Council operate a milestone driven monitoring process in which the milestones are often set by the panel and have scientific outputs that form gateways to progress to the next project phase. Each of the approaches has pros and cons. Aggregated performance management in the Medical Research Council is organised by regular meetings revisiting live projects on RAG rating whereas the Innovate UK’s approach is more pragmatic, monitoring RAG rating of projects against their project plan, and focused on solving issues as they arise.

The differences between Medical Research Council and Innovate UK processes partly reflect differences in the organisations’ focus and their key audiences. Despite having a systematic approach where the monitoring officers
flag any issues to the Lead Technologist, there may be scope nevertheless to incorporate additional scrutiny of scientific progress into Innovate UK processes.
6 Baseline and Early Evidence of Impact

This section reviews the early findings from the research on the impact of the Biomedical Catalyst to date. The evidence presented here primarily draws on the survey of applicants and the preparation of 20 applicant case studies. It has also been informed by the stakeholder interviews and other opportunities which the study team have had to engage with applicants, such as participation in a BioIndustry Association dinner in February. This analysis will be updated following a second wave of survey and case study interviews in 2018.

6.1 Technological Progress

Projects funded through the Biomedical Catalyst have seen some progress since notification of the award. The applicant survey suggested that the proportion of projects at the stage of clinical trials has doubled (from 14 to 28 per cent), with similar progression from exploratory stages to in-vitro and in-vivo experiments or their equivalents. The results suggested that a small proportion of projects were complete at the time of the survey (14 per cent), with a similar proportion in their later phases.

The case studies also identified considerable progress being made by successful applicants. Examples ranged from applicants who had taken a therapeutic agent through the first steps beyond proof of concept, to one who would use Biomedical Catalyst funding to complete and analyse a stage II trial, assessing the efficacy of a therapeutic intervention. Case studies of CiC programmes identified a number of projects where investment had helped to deliver the additional tests necessary for principal investigators to have confidence that they would now be able to secure further follow-on funding.

6.1.1 Project Progression

The applicant survey suggested that successful applicants were both more likely to have advanced their projects since the application was submitted, and more likely to have progressed further to market than unsuccessful applicants. Over 50 per cent of projects put forward by unsuccessful applicants had been postponed or terminated early, compared to 13 per cent amongst successful applicants. All relevant successful applicants and 72 per cent of relevant unsuccessful applicants cited difficulties in securing finance as the main reason they had terminated the project early. Some unsuccessful applicants also reported concerns over the future cost of R&D activity, and expectations of future returns, as factors in their decision making. No survey respondent reported that failure to meet pre-clinical or clinical milestones was a reason for terminating the project early. However, this was identified as an issue in one project case study.

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44 As detailed further in Annex C, the applicant survey asked applicants to describe their technical progress against a TRL scale
45 See Annex E
What is the current status of the project as defined in your application for Biomedical Catalyst funding?

Source: Survey of Applicants

It is worth noting that case study interviews suggested that many successful academic applications were associated with a considerable delay between initial application and project commencement. For example, one successful academic applicant was planning to start their project in May 2015 with a delay of approximately a year from initial application, reflecting the timeline involved with the selection process and because during that time a key team member had changed institution and was no longer available for the project. From the case study interviews, it appears that academic applicants were unlikely to progress their projects while awaiting funding outcomes, and in many cases are prohibited from applying to multiple funding sources concurrently. The survey data presented above includes only applicants up to round 6. We might expect that what are ultimately successful applications show slower progress in the six or 12 months after application. Nevertheless, the results of the survey show that projects from successful applicants have been proceeding to market at a faster rate than those from unsuccessful applicants:

- **Progression to in-vitro and in-vivo studies**: At the point of application, some 73 per cent of projects were at the earliest development stages (TRL 1 to 3), falling to 39 per cent at the point of the survey. This was accompanied by a parallel growth in projects at the point of in-vitro (TRL4) or in-vivo (TRL5) studies from 13 to 32 per cent.

- **Clinical research**: The proportion of projects at clinical research stages overall (TRL6-8) rose from 14 per cent to 28 per cent. The proportion of projects at the point of efficacy trials (TRL 6-7) rose from 13 to 23 per cent. While these signs are positive, it also suggests that it will take time before there is significant commercialisation of the project portfolio (with some 72 per cent of projects at pre-clinical stages in February or March 2015).

Progress amongst projects put forward by unsuccessful applicants was less rapid. The proportion of projects at TRL1 to TRL3 fell from 71 per cent to 61 per cent, with the share of projects at in-vitro or in-vivo study stages rising from 21 per cent to 26 per cent, and those at clinical stages rising from 9 per cent to 13 per cent (with almost no
change observed in the proportion at efficacy trials). Figure 6.2 illustrates these differences, comparing the progress of projects for successful (left hand side) and unsuccessful applicants (right hand side).

Figure 6.2 – Distribution of projects by TRL level at the point of application and Feb/ Mar 2015

Further analysis of this data identifies the following variations within the sample:

- **Type of applicant**: Projects led by firms have progressed more rapidly (both in absolute terms and relative to unsuccessful applicants). Projects led by academics have progressed less rapidly and with a smaller differential between the rate of progress of successful and unsuccessful applicants (though this may be partly due to the fact that Feasibility Studies are only delivered by firms).

- **Type of award**: The greatest rates of progress are visible amongst Feasibility Studies, with Early stage studies showing the least rapid progress (both in absolute terms and relative to unsuccessful applicants).

- **Product type**: Projects focusing on diagnostics and medical devices have progressed more rapidly than projects focusing on the development of new therapeutics.

It appears that successful projects are generating more positive results. A larger share of successful applicants reported that project results to date were supportive of the initial scientific hypotheses than unsuccessful applicants.

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*Speculatively, this may be due to a range of factors. Firstly, regulatory requirements differ for medical devices, allowing progress through the TRL stages more rapidly and at lower cost. However, this is not necessarily an indicator that the product will be commercialised more rapidly. Finally, progress against the TRL scale is self-reported; there may be differences across different product types in how applicants viewed their progress towards commercialisation.*
applicants (72 per cent and 58 per cent respectively). The remainder largely reported that it was too early to judge. A minority of applicants reported that the results had led to some concerns about the future of the R&D project (indicating the presence of some future risks), as illustrated in the figure below.

Figure 6.3 – And do the results to date raise any concerns …

Source: Survey of Applicants

6.1.2 Perceived effect of Biomedical Catalyst funding

Successful applicants to the Biomedical Catalyst felt that if they had not secured funding they would have found it difficult to continue or deliver their projects. Almost 70 per cent of successful applicants who responded to the survey reported that the project would not have meant going forward in any form without Biomedical Catalyst funding (illustrated in figure 6.4). The applicant survey identified that only a very small proportion of successful applicants felt that they would still have continued without Biomedical Catalyst funding.

A number of case study applicants suggested that their projects were at a stage at which they would have been unable to secure venture capital funding because their projects were not sufficiently advanced and were ‘too risky’ for private investors. In certain market segments it was suggested that there were a set of minimum requirements for private investment – a validated target with high quality antibodies, for example – without which projects could not hope to secure funding.

For one case study, the applicant securing approval from Innovate UK was central to obtaining internal sign-off to pursue the project. This was presented as delivering external scientific verification of the proposal and seen as a key condition placed on the team by their company board in approving the team’s proposed strategic shift from a Contract Research Organisation developing projects on behalf of pharmaceutical companies and developing a set of their own long-term projects. Another had already approached their current investors to support the project without success and was unwilling to draw in additional investors for fear of further diluting the equity pool. For these case study applicants it appears that securing Biomedical Catalyst funding was critical to their perceived ability to take their projects forwards.
A second group of case study interviewees, however, suggested that they might have been able to find alternative sources of funding for their projects but that this would have gone forward in some modified form. Two applicants suggested that had their applications been unsuccessful they would have still continued with their projects, but at a slower pace. One suggested that the project might have plodded on more as a ‘hobby’ or ‘pet’ initiative supported by internal company resources rather than a full scale translational research project. Another company suggested that they had a portfolio of related projects, and had their application been unsuccessful this project would have been ‘put on the back-burner’. More than one academic applicant suggested that they would have applied for funding for a similar project from another source such as the Welcome Trust or the British Heart Foundation though there was a strong sense that doing so would have resulted in a smaller project, and could have caused significant delays. One of these applicants felt strongly that this potential reduction in the scale of the project could have had a significantly disproportionate negative impact. Having sufficient funding to take the project through to a full scale efficacy test was seen as essential. In the case of their work, stop-start or drip-drip funding wasn’t considered viable.

In the survey, successful applicants were asked to report whether their project would have proceeded in any form without Biomedical Catalyst funding, while unsuccessful applicants were asked to describe whether they had been able to do so following rejection. This allowed for a comparison between these two groups and helped explore the reliability of the successful applicants’ conjecture about what they would have done had they not received funding. Where respondents reported that they would have taken (or were able to) take the project forward, they were asked to describe whether there would have been any material changes in the project’s timing, location, scale, or scope. The responses given by successful and unsuccessful applicants diverged substantially: only one third of successful applicants reported that they would have otherwise taken the project forward, while two thirds of unsuccessful applicants reported that they were able to do so.

Where successful applicants reported that they would have been able to take the project forward in the absence of Biomedical Catalyst funding, they generally reported that it would have gone ahead with delays, at a reduced
scale of investment, or with reduced scope. This broadly matched the pattern of responses given by unsuccessful applicants, though around 20 per cent of unsuccessful applicants indicated that they had taken the project forward without any changes following their rejection for Biomedical Catalyst funding.

Unsuccessful case study applicants reported a broadly similar picture to the survey respondents:

- **Project delays** – One applicant had received feedback that their application had been too broad and were anticipating a considerable delay while they resubmitted. Another applicant anticipated that they would ultimately secure project funding, but that the delay was a significant issue because they were pushing closer to the expiry date for one of their project partner’s patents.

- **Pursued abroad** – Some of the unsuccessful applicants were now considering attempting to secure funding for their projects abroad. There were a mix here of specific leads for funding, and more general assertions that funding could be secured in other countries. One unsuccessful case study applicant had applied in partnership with a South East Asian organisation and understood that they would be continuing with their component of the project regardless of the funding decision.

- **Reduced scale or scope** – One applicant was now planning on approaching a charity for funding, but expected this to result in a project which was an order of magnitude smaller than that for which they had applied.

### 6.1.3 Impact of rejection on unsuccessful applicants

Unsuccessful applicants identified a range of adverse effects associated with rejection of their application by the Biomedical Catalyst. The survey of applicants (figure 6.5 overleaf) identified that rejection had caused project delays (13 per cent), the loss of key R&D personnel (13 per cent), and seeking other funding (9 per cent). As identified in section 6.1.2, an important effect is that unsuccessful applicants may re-focus their attention on other projects as a result of a negative funding decision. This was immediately identified as an effect of rejection by ten per cent of respondents. Those that did not mention that they had increased their focus on alternative projects were asked directly whether they had done so, and almost 80 per cent reported that this was the case. This suggests that 90 per cent of unsuccessful applicants had increased their focus elsewhere.

This effect was also evident within the case studies with a number of unsuccessful applicants discussing their portfolio of assets or projects and offering optimism about the potential for other parts of the business or research group. Finally, successful applicants strongly suggested that rejection from this sort of application can negatively impact on the standing of an academic within their Department. Although this was not directly identified by unsuccessful applicants as an issue, this may also have been an impact of rejection.
Figure 6.5 – Impact of rejection on unsuccessful applicants

Source: Survey of Applicants

6.2 Research and Development Activity

6.2.1 Project Level R&D expenditure

On average, research and development investment increased for both successful and unsuccessful applicants between the point at which they submitted their application, and the time of the survey. As illustrated in figure 6.6 overleaf, this change was larger for successful applicants than those who were unsuccessful. However, prior to their application, successful applicants had (on average) invested more than double the amount in research and development on their projects than unsuccessful applicants (£1.8m versus £0.6m), and the proportionate growth was smaller for successful applicants relative to unsuccessful applicants. Amongst those able to provide validated figures for both periods, total reported cumulative investment in the projects rose from £141m to £205m amongst successful applicants, and from £62m to £105m amongst unsuccessful applicants.\(^{47}\)

\(^{47}\) These figures are based on unweighted data. Applicants to rounds 5 and 6 are included in these totals, though it is assumed that project expenditure saw no change over the period.
Figure 6.6 – Change in R&D investment in the project forming the focus of the application to the Biomedical Catalyst

The survey data shows that absolute R&D expenditure rose more rapidly amongst successful applicants, regardless of whether the project was led by academics or firms. Percentage growth in R&D expenditure was similar across successful and unsuccessful academic-led projects (at around 60 to 65 per cent), and more rapid for unsuccessful than successful firm-led bids (65 per cent compared to 38 per cent). R&D investment in the project rose faster amongst successful than unsuccessful applicants in absolute and proportionate terms for both feasibility and Late Stage awards. For Early Stage awards, absolute changes in expenditure were similar across successful and unsuccessful applicants (growing by 41 per cent amongst successful applicants and 115 per cent amongst unsuccessful applicants).

The case study evidence from successful projects on securing additional funding during or since the project ended was relatively sparse. One explanation for this is that for academics, under Medical Research Council rules the grant holder is not allowed to receive support for the same project until it is complete. There was one instance in which the academic had not secured any additional funding but their industrial partner was able to raise additional funding during the project. One of the successful industrial applicant projects selected for a case study indicated that the project enabled them to become credible for other key funding sources and to secure funding. Another SME indicated that the work undertaken since the grant has been funded through internal shareholder investment. The plan was to continue to fund it within the business and refrain from losing equity. This grant holder was clear that once they have been able to demonstrate that the technology is working effectively; they will start seeking partners for very specific applications, as well as selling defined products which are an advancement on what they are already selling. The aim was to create new product generations from the technology and to enter into collaborative licensing deals. This highlights further that most of applicants’ efforts were however focusing on achieving project milestones and progressing along the developmental pathway rather than securing additional resources.
6.2.2 Broader Changes in R&D activity

The applicant survey indicates that successful applicants were able to increase the number of R&D projects that they are involved in, following their successful application. Unsuccessful applicants saw no positive change in the number of R&D activities but had on average been involved in more projects at the time of their application. This result appears to be driven by both, academic and industrial applicants. Successful applicants across all three types of awards saw an increase in the number of their active R&D projects relative to unsuccessful applicants.

The survey indicated that the successful applicants’ R&D spending rose by 14 per cent between the time of the application and the time of the survey (from £1.3m to £1.5m per annum) while remaining largely unchanged for unsuccessful applicants (at £0.6m). For those able to provide valid figures in both periods, total annual R&D expenditure reported by successful applicants rose from £100m to £112m, and from £79m to £80m amongst unsuccessful applicants. Growth in spending on the project forming the focus of the application to the Biomedical Catalyst also outpaced growth in total R&D spending (suggesting applicants either diverted resources to these projects from other R&D projects, or that other R&D projects had come to a conclusion and had not yet been replaced by new projects). This growth was largely driven by academic applicants.

Both successful and unsuccessful academic applicants were focused mainly on translational research at the point of their application (80 per cent of the research projects both groups were involved in had a translational focus). There was no material change in this measure of focus on translational research by the time of the survey for either group. Case studies indicated that the academic-led applicants were all experienced researchers with a translational focus; however, on a number of occasions they partnered with experts in basic research or engineering.

Figure 6.7 – Changes in number of R&D projects, annual R&D spending and (academic applicants only) projects with a translation focus

Source: Survey of Applicants

48 These totals are based on unweighted data.
Case study applicants identified a range of effects of securing funding on their organisations ability to pursue new R&D opportunities with impacts on their overall research spending:

- **Operational learning relating to winning the project** – The study team successfully responded to challenges around recruiting a patient population and finding the right sites to conduct research. These approaches can be easily re-applied on subsequent projects.

- **Positive reputational impact from receiving the grant** – one of the successful applicants who is currently seeking equity funding for the next stage of the project stated that “Biomedical Catalyst has made the equity finance easier to access.”

- **Capacity building** – Involvement of research staff in the challenging and scientifically complex study (i.e. Biomedical Catalyst project) enabled the applicant to “keep a certain level of resource on board” which in turn improves ability to bid for similar projects.

### 6.2.3 Research and development supply chain effects

Respondents to the survey (whose projects project had not been terminated early or postponed) were asked to report whether they had made use of Contract Research Organisations (CROs) or Manufacturing Organisations (CMOs) in the delivery of the their project. Overall, 56 per cent of successful and 45 per cent of unsuccessful applicants reported that they had used CROs or CMOs to deliver the project. Usage of CROs and CMOs was more prevalent amongst firm led than academic-led bids, amongst Late Stage bids (likely linked to clinical trials in humans), and for projects involving the development of therapeutics.

Respondents were also asked to report the percentage of project development costs spent with CROs and CMOs based in different geographical territories. Successful applicants spent a higher proportion of contracting costs on UK based suppliers than unsuccessful applicants (82 per cent compared to 63 per cent). In turn, unsuccessful applicants spent a greater proportion of contracting costs on suppliers based outside the European Union (nine per cent compared to 25 per cent).
Evidence from case studies highlighted that an academic leader could pursue the research project with use of a CRO but receiving a Biomedical Catalyst grant allowed them to form a collaboration with a firm and have access to their expertise and methodological approaches - “the real collaboration with the industrial partner resulted in knowledge sharing and the team learnt much about applying methods.” In another case study, an academic used a CRO from India to perform chemical analysis and complimented the effectiveness of this approach. One case study interviewee mentioned the benefits realised by staff involved in the projects through networking with contacts at the research sites.

6.3 Funding

6.3.1 Sources of funding for projects

At the point of application, successful applicants had previously secured an average of £1.4m in project funding, while unsuccessful applicants had secured an average of £0.8m. Firms had secured approximately double the funding levels of academics, while funding levels increased in line with the levels of technical development implied by the different stages of award. Projects involving the development of therapeutics tended to have attracted the highest levels of funding at the point of application.

The funding profile of successful and unsuccessful applicants were broadly similar, though successful applicants tended to have drawn down a higher proportion of funds in the form of grants from the public sector (30 per cent compared to 20 per cent), and a smaller proportion of funds from profits (27 per cent compared to 38 per cent). The proportion of funds drawn from investment from venture capitalists and business angels was broadly similar.
Case study interviewees were to a large extent highly experienced applicants for public and charitable funding. A diverse mix of sources has been used to date to invest in Biomedical Catalyst applicant projects including:

- Innovate UK (or Technology Strategy Board) grants
- Funding from the regional sources (Welsh Assembly Government, Scottish Enterprise)
- Resource contributions from universities for spin-out companies both in terms of staff and facilities
- Charities including the British Heart Foundation, Thrombosis Research Institute and international charities such as the Michael J Fox foundation or the Bill & Melinda Gates Foundation.

Some of the companies have already had venture capital funding but were not willing to dilute their equity further. Investigation by the Medical Research Council (at the time of the survey) indicated that approximately half of the SME applicants have an academic origin (spin-off). In our case studies we have encountered an example where it was challenging to disentangle the role of investment and funding for related IP and products from the results of the current Biomedical Catalyst project (For example, one team was developing a related medical device for use in two parts of the body).

### 6.3.2 Funding Post Application

The applicant survey indicated that overall 35 per cent of successful applicants and 45 per cent of unsuccessful applicants had been able to secure additional funding since their application to the Biomedical Catalyst. However, this varied substantially by type of applicant. More than half of unsuccessful academic applicants (53 per cent) found alternative sources of funding, compared to nine per cent of successful applicants — again this might be partly explained by the Medical Research Council funding rules that apply to grant holders. Alternatively, it might mean that the Biomedical Catalyst funding satisfied applicants’ funding requirements, removing the need to seek additional finance.
Applicants were asked a similar question with respect to their current funding levels. Overall, average funding levels for successful applicants rose by 56 per cent (or £800,000), while increasing by 35 per cent amongst unsuccessful applicants (around £300,000). Around 55 per cent of the observed growth in funding levels was driven by venture capital investment or investment by business angels. For those able to report figures in both periods, total reported funding levels (excluding Biomedical Catalyst awards) rose from £292m to £484m amongst successful applicants, and from £82m to £120m amongst unsuccessful applicants.

Figure 6.10 – Funding levels at point of application by source of funding

The case studies provided supporting evidence for how the successful applicants were able to secure further funding:

- In the one example, a medical device company was able to increase the scope of their activities by helping to fund staff time to publish more about the device and to attend more events to publicise their work.
- A number of case studies outlined how, prior to applying, applicants went on to pursue matched funding for the Biomedical Catalyst project by investors. One explained further that once the project was up and running, the same investor who previously refused to increase their investment approached them to suggest that they invest more.
- One of the holders of the Biomedical Catalyst grant stated that the Biomedical Catalyst approval badge made going for funding easier to access. “There is no doubt that the Biomedical Catalyst awards carry quite a lot of kudos… it carries an element of a stamp of approval”
- A number of Confidence-in-Concept programmes administered by the universities have a specific focus on securing follow-on funding, either by pursuing full Biomedical Catalyst applications or other types of funding (European funding or private funding). These case studies exemplify that some of these funds have been...

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49 These figures are based on unweighted data.
highly successful, with one of the universities’ supported 8 projects, 6 have already subsequently received additional funding including one Biomedical Catalyst grant.

One of the investors consulted, who runs a network of Angel investors, suggested that a Biomedical Catalyst grant “definitely helps with investors” as it is rare to have committed funding at an Early Stage. Another investor further suggested that Biomedical Catalyst funding can help a company to stand out, in addition to de-risking the balance sheet.

6.4 R&D employment

Alongside measures of R&D spending, respondents to the survey were also asked to report how many R&D workers (or team members in the case of academic applicants) they employed at the time of their application to the Biomedical Catalyst and the time of the survey. On average, R&D employment grew by 21 per cent between the application and the time of the survey amongst successful applicants (from an average of 10.8 to 13.1) and by 14 per cent amongst unsuccessful applicants (from 8.0 to 9.1). For those able to provide figures for the two periods, total reported R&D employment rose from 740 to 920 employees amongst successful applicants and from 840 to 920 amongst unsuccessful applicants50.

In terms of differences across groups:

- **Applicant type:** Successful and unsuccessful firms both grew their R&D employment by 21 per cent (though unsuccessful firms tended to employ fewer R&D workers, and saw small absolute growth in R&D employment). Unsuccessful academic applicants saw no change in the overall size of their research teams, while successful academic applicants grew their teams by 23 per cent (from 8.7 staff on average to 10.6).

- **Award type:** R&D employment grew most rapidly amongst successful applicants for Late Stage awards (around 47 per cent, from 11.8 workers to 17.4 workers, compared to 11 per cent amongst unsuccessful applicants). Successful applicants for feasibility and Early Stage awards saw R&D employment grow at 12 and 16 per cent respectively, in comparison to 25 per cent and 7 respectively amongst unsuccessful applicants.

- **Product type:** R&D employment rose most rapidly amongst applicants focused on the development of medical devices (despite reductions in annual R&D spending), by around 33 per cent for both successful and unsuccessful applicants (equivalent to 2.3 and 3.9 workers respectively).

Growth in total R&D employment tended to outpace expenditure amongst successful applicants and unsuccessful academic applicants (for unsuccessful firm led bids, R&D employment rose in line with expenditure).

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50 These totals are based on unweighted data.
Figure 6.11 — Change in R&D employment

Source: Survey of Applicants

6.5 Funding Landscape

As discussed in section 3.1 above, the supply of capital in 2011 was severely constrained. A large number of individuals contacted as part of the evaluation research strongly believed that the funding from the Biomedical Catalyst had helped to ease this situation in 2011. Several applicants and one stakeholder suggested that the Biomedical Catalyst had ‘saved the sector’ by providing investment funding at a time when it was in very short supply. As also noted above, it appears that the funding landscape has improved markedly, especially in the past 12 months. Stakeholders were able to identify the Biomedical Catalyst as one of the contributing factors to this improvement, alongside sustained public investment in science, investment and research tax reforms. However, they found it more difficult to identify the relative significance of these factors.

At the close of the evaluation assessment period, the Biomedical Catalyst has committed £201m of public funds to projects worth a total of £310m over the period 2012 – 2018 (£33m and £50m per year respectively). This represents a small share of the annual £4bn research and development expenditure identified for the sector in 2013. The potential for the programme to have an impact is enhanced when the spending is compared to the £214m VC investment made in 2013 (though as noted above, this may have increased significantly last year). One investor noted that, despite the Biomedical Catalyst investment, UK public spending in this area lags behind what is seen as the UK’s main comparator country - the US. It was suggested that the funding for the Biomedical Catalyst compares unfavourably with a recent announcement of a $1bn public fund for translational research in life sciences in Massachusetts alone. It was also identified that the US scheme came with an eight year funding plan which was perceived to be much more attractive to investors, and will potentially have a much greater impact on the investment landscape than the four years allotted to commit R&D grants through the Biomedical Catalyst.

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51 Benchmarks drawn from Section 3.1.
6.6 University-Industry Collaboration

6.6.1 Patterns of Collaboration

This section considers the extent to which the programme has supported the development of stronger relationships between academics and business. A majority (approximately 70 per cent) of funded projects were submitted by a single academic or firm lead with no nominated collaborators. This focus limits the potential impact of the programme to deliver enhanced collaboration outcomes. However, analysis of the survey of applicants identifies a larger share of unsuccessful applicants which had collaborated across the industry-university divide. More generally:

- 50 per cent of academics collaborated with a commercial partner on the project prior to their application.
- 32 per cent of firms worked with an academic partner on the project prior to their application.
- 57 per cent of successful applicants worked with a partner on the project prior to their application from a different sector (i.e. academics with firms and firms with academics).
- 65 per cent of unsuccessful applicants worked with a partner on the project prior to their application from a different sector (i.e. academics with firms and firms with academics).

This comparative performance of joint academic-firm applications does not necessarily imply that these applications are more difficult to deliver to a high standard, or are viewed less favourably in the selection processes (neither of these effects was identified during the process evaluation). The difference may be driven by a number a factors, including a consortia size effect. As illustrated in figure 6.11, collaborative applications in general appear to have a lower success rate than those specifically involving individual academics and firms. It has not been possible to establish the extent to which this is a cause of less successful applications, or whether larger consortia tend to be driven by a lack of confidence in an application.

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52 This estimate draws on analysis of monitoring data, which as previously noted underestimates level of collaboration in academic-led projects.
Case study interviews identified a broad range of motivations underpinning these collaborations. For firms, as anticipated in section 5.8 above, the opportunity to secure 100 per cent funding was an important issue (i.e. no match contribution was required); for academics time was an important consideration. This was seen as a way to save costs or to boost the size of the project that could be taken forward with a fixed internal resource. This opportunity was seen as especially appealing for applicants involved with spin-out companies with a close relationship with a university where staff worked for both the university and the spin-out. More generally, firms were partnering with academics to draw on particular areas of expertise (typically clinical), as well as to help with navigating regulatory and other compliance issues (academic institutions were understood to be treated differently here to companies). For a number of academic applicants the primary reason for working with firms was to gain access to specific engineering capabilities and capacity. Others identified that the firm they were partnering with had particular expertise in seeking relevant regulatory approvals.

6.6.2 New collaborative relationships

Focusing on new collaborative relationships, the survey of applicants found that approximately 50 per cent of both successful and unsuccessful applicants reported forming a new collaborative relationship to take their projects forward. It is possible that some of these new relationships were formed from the application process itself. Figure 6.12 below focuses on the average number of new collaborations formed during the application process. It illustrates that successful firms were in fact less likely than unsuccessful applicants to have formed new relationships with academics, while successful academics bidders were no more likely than unsuccessful applicants to form new relationships with industrial partners.
The programme may have an impact on the quality of collaboration in the sector by strengthening existing relationships. This was not explored in the survey so is difficult to quantify. The effect was however clear in two of the 20 case studies. In one the project enabled the company to have more strategic conversations with the pharmaceutical companies with which they already worked. In the other the applicant suggested who they previously had contact with their academic partner, but had not worked with them on a collaborative project.

From interviews with applicants, however, it appears that a new direct collaboration impact is not likely to be a primary effect of the programme within academia. The programme appears to be supporting academics that already have a significant orientation towards translational research and experience of working with commercial partners. Typically academics interviewed as part of case studies had experience taking therapeutics or devices into a clinical trial environment in partnership with large companies. Some had previously been involved with treatments which were already in the market place. Several were from specific translational research departments funded by either the Medical Research Council or the NHS - for example, one academic applicant who had held multiple research fellowships, had strong institutional links to a hospital and had previously held a Yorkshire Forward enterprise fellowship. Many of the academic-led applicants also mentioned their experience in founding early stage companies.

Similarly, the overwhelming majority of firms contacted by the study team had a good understanding of, and experience of, working with academic partners. Many had previously been academics and formed spin-out companies, or worked with academics to acquire intellectual property. In many instances it was clear that academics were working with commercial partners with whom they had had a long relationship, and that these partners were used to working with the academics and this was a core component of their business. Underlining the importance of the experience of this group of individuals, working across both industry and academia, one applicant noted that: “The major reason why I decided two years ago to move most of my activities to the UK was that we require a lot of collaborative studies with universities and British universities are very approachable in that sense and it is very easy to find academic partners.”
Rather than delivering a direct impact on university-industry collaboration, through investing in new collaborations, this programme could be having an indirect effect. If it is supporting this group of experienced collaborators, then it may be acting to increase the opportunities for junior academics to enter this space, as well as boosting their incentives to do so. This effect is, however, beyond the scope of this evaluation, and likely to be influenced by many of the factors discussed in section 3.2.

6.6.3 Benefits of Collaboration

Respondents were also asked to describe the benefits that these new collaborative relationships had brought to the project. The survey results indicate that new relationships formed by successful applicants had been more productive than those formed by unsuccessful applicants, particularly with regard to improving their understanding of the basic scientific principles involved, patient needs, and understanding of regulatory requirements. This could be expected given the different rates of progress discussed in section 6.1 above.

Figure 6.14 – Benefits of Collaboration

Source: Survey of Applicants

6.6.4 Broader collaboration effects

The final aspect of collaboration explored in the survey was applicants’ involvement in R&D projects with academic or commercial partners more generally. Respondents were asked to report on how many R&D projects they were engaged in which involved an academic or commercial partner, both at the point of application and at the time of the survey. The survey findings did not suggest that any material changes in participation in collaborative projects had occurred between the application and the time of the survey. There were no marked differences between successful and unsuccessful applicants (other than the finding observed above - that successful firms were less collaborative in focus than their unsuccessful counterparts).
6.7 Intellectual property, patenting and publications

6.7.1 Intellectual property landscape prior to application

It is apparent from the case studies that each application to the Biomedical Catalyst is associated with a broad range of existing intellectual property assets. High proportions of applicants had either filed a patent shortly prior to application, or were working within the confines of an existing patent. More than half of all survey respondents reported registering intellectual property prior to their application to the scheme. As expected, given the funding points noted above, these IP assets were most significant for successful applicants.

Respondents to the survey were asked to report on how far they had registered any intellectual property (IP), with respect to the project forming the focus of their Biomedical Catalyst application. Successful applicants were more likely to report that they had registered intellectual property prior to their application to the scheme (66 per cent of applicants) than unsuccessful applicants (56 per cent). Those who had registered intellectual property were also asked to describe how far ownership of that intellectual property was shared with collaborators. Successful applicants were more likely, than unsuccessful applicants, to have sole ownership of the intellectual property (74 per cent compared to 66 per cent). Few applicants had had the Intellectual Property valued (12 per cent of successful applicants compared to 18 of unsuccessful applicants), and just eight respondents were able to state the valuation of that of IP (ranging from £10,000 to £50m). A total value of £96.6m was reported by successful applicants (an average of £19.6m), and a total value of £53m by unsuccessful applicants (average value of £17.6m).53

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53 Note that these figures are based on unweighted data.
6.7.2 Intellectual property outcomes from the projects

The applicant survey identified that a significant number of applicants had filed IP as a result of the project. Respondents to the survey were asked to report on how far they had registered any new intellectual property since submitting their application to the Biomedical Catalyst. Similar proportions of successful and unsuccessful applicants (who had not terminated their project) reported that they had done so (27 per cent and 33 per cent respectively). Few had at that point had the IP valued (no successful applicants and two unsuccessful applicants registering IP). Additionally, no successful applicants (and one unsuccessful applicant) indicated that they had sold the IP.

These results may understate the IP impact of the programme. One case study applicant was planning on shortly filing a patent application following a Feasibility Study. Another had filed a patent prior to applying to the Biomedical Catalyst, but reported being able to use results from their funded research to strengthen the patent and to improve their likely ability to defend it in future by adding detail which will enhance the replicability of results. The case studies also identified an example of a key IP outcome which will not be registered. This was a project where the clinical results from the research, funded by the Biomedical Catalyst, will be the company’s key intellectual property. This will generate a unique dataset and the use or sale of that data will be key for the owner’s exit strategy. This is a database that can only be protected through non-disclosure rather than registration.

6.7.3 Spin-outs, sale of firms and licensing agreements

Respondents to the survey were asked to report whether they had established a new commercial entity to exploit the IP generated through the projects forming the focus of the Biomedical Catalyst, sold their firms, or entered into any licensing agreements since their application:

- **Spin-outs**: Just over 20 per cent of both successful and unsuccessful applicants reported that, since receiving Biomedical Catalyst funding, they (or their academic institution) had created a commercial entity to exploit the product being developed
- **Sale of firms**: No respondent to the survey indicated that they had sold their firm or commercial vehicle onto another buyer.
- **Licensing agreements**: Six per cent of successful applicants and 17 per cent of unsuccessful applicants reported that they had entered into licensing agreements. Just six respondents were able to report the value of these agreements (with a range reported of between £100,000 and £100m\(^4\)). The average and total value of these agreements was £35m and £104m respectively in the case of successful applicants, and £320,000 and £950,000 in the case of unsuccessful applicants\(^5\).

6.7.4 Publications

Respondents to the survey were asked to report on how far the project had resulted in any research outputs in the form of conference papers, presentations at events, article submissions to academic journals or publications in academic journals. As suggested in the figure below, there were significant differences between successful and unsuccessful applicants, with higher proportions of unsuccessful applicants producing these types of research outputs from the project (with the exception of conference papers).

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\(^4\) The validity of this outlying value of £100m was checked against news reports on the website associated with the respondent in question, and the observation appears plausible.

\(^5\) These figures are based on unweighted data.
Interviews with applicants offered a range of possible explanations for these findings relating to what applicants felt they could publish. These reflect the complex set of incentives and opportunities associated with research outputs. Several academic applicants suggested that the delivery of translational research projects was often not associated with the production of highly rated journal articles. They suggested that early and more exploratory stages of technical development may produce more in the novel research findings, suitable for this form of dissemination, than the delivery of dosing or increasingly robust animal models. One of these applicants noted that they had already delivered the key academic outputs from the project prior to the application, at the point at which the IP was first registered.

Another applicant indicated that they were delaying the production of research outputs in their work because their grant had been successful. This meant that they would soon have access to more developed research findings which would help to deliver a stronger research output and publication in more highly rated journals (an option that might have had to be ruled out had they published less developed results in a lower status journal). The delivery of a Biomedical Catalyst award is evidently a time intensive activity for many applicants which could potentially also divert attention away from the production of research outputs. Additionally, reduced publication rates could also reflect commercial secrecy, as publications qualify as ‘prior art’ and could affect scope to patent where filings had not yet been made (for example, to maximise the life of the patent). However, this was not an issue flagged by any applicants during case study interviews.

6.8 Organisational Development and Capacity Building

Across all types of applicants the case study and qualitative interviews identified a range of organisational benefits arising for successful applicants. Academics in particular were keen to stress the capacity and capability benefits arising from their projects. Benefits include:
• **New assays** – one CiC supported project hired a new post-doctoral candidate who developed new assays which the whole team are using

• **New capacities** – one project is helping to set up the facility to deliver a new type of animal test. This will be the first centre in the UK to have this capacity and will enhance the capacity of a leading research centre

• **Experience** – one applicant felt that the experience of pursuing the project had helped develop the ability of his team to pursue large antibody research projects. This experience point was identified even where the project disproved the original research hypotheses.

In addition to citing a range of related organisational learning points, firm applicants were particularly keen to stress the beneficial halo effect that a successful application to the Biomedical Catalyst has had. In addition to the leverage points discussed above, it was suggested that the Biomedical Catalyst ‘badge’ had been good for branding, that it had acted as an external ‘stamp of approval’ which was important for securing new collaborative partners, and had even lead to staff approaching the company and expressing interests in working on the programme.

The Biomedical Catalyst was also identified as supporting a change in strategy amongst two successful applicants where organisational choices were made contingent on securing the funding and critically, what was seen as an accompanying seal of approval for the scientific content of project. In one case, securing the Biomedical Catalyst grant was used to support a change in strategy for part of the organisation from a role as a contract research organisation towards a more equal and collaborative partner with pharma in the development of diagnostic tools. This was identified as supporting a shift towards higher value added activities. The possibility of long term funding from the Biomedical Catalyst was also identified as helping to raise the ambition of companies, and helping them to retain staff. In one case study funding was linked to the ability of the organisation to start offering a salary to its directors.

### 6.9 Economic Effects

As suggested above, while positive progress had been made by successful applicants in progressing projects towards the market, commercialisation of the projects forming the focus of the Biomedical Catalyst has yet to be achieved in significant numbers. As such, it likely to be too early to begin exploring the economic impacts of the scheme (in the form of higher output (GVA), productivity or employment). However, the survey was used to collect baseline measures of turnover and employment (and early indications of change) that will be re-examined at a later stage. These following sections focus on projects led by firms.

#### 6.9.1 Turnover

Respondents were asked to report the value of their annual sales at the point of their application and at the time of the survey. A high proportion of respondents reported that their annual turnover was zero at both points in time (71 and 69 per cent); successful applicants to the scheme tended to report higher levels of turnover than unsuccessful applicants. The sales of successful applicants rose by 25 per cent over this period (from an average of £1.3m to £1.7m). The total turnover reported by successful applicants (amongst those able to give figures for both periods) rose from £71m to £80m, while falling from £41m to £37m amongst unsuccessful applicants. At the same time, sales fell by ten per cent amongst unsuccessful applicants. However, given that no applicants had brought a new product to market, it is not anticipated that these changes can be linked to the Biomedical Catalyst unless linked to licencing of IP.
Figure 6.17 – Changes in turnover between application and February / March 2015

Source: Survey of Applicants

6.9.2 Employment

Similar patterns of employment change between the point of application and the time of the survey were observed on average amongst the successful and unsuccessful applicants, with growth of 26 per cent and 20 per cent growth respectively. For those able to report for both periods, total employment rose from 930 to 1,170 workers amongst successful applicants and from 960 to 1,150 workers amongst unsuccessful applicants.
Changes in overall employment were highly correlated with changes in the employment of R&D workers, suggesting that the changes observed are more closely linked to R&D activity than production (and as such, it is anticipated that the overall change in GVA may be negligible amongst both groups).

**6.9.3 Future Exploitation Plans**

Respondents were asked to describe their future plans for the project. 91 per cent of successful applicants and 85 per cent of unsuccessful applicants reported that they planned to continue with research and development into the project that formed the focus of their application to the Biomedical Catalyst:

- **Reasons for project termination:** The proportion not intending to continue with their projects was highest amongst feasibility awards (14 and 23 per cent of successful and unsuccessful applicants respectively) and projects focusing on the development of diagnostic tools (16 and 15 per cent of successful and unsuccessful applicants respectively). When asked why they would not be proceeding with the project, successful applicants most often cited issues with their project hypothesis or that its rationale was now invalid. For unsuccessful applicants the main reason cited was difficulty in raising finance.

- **Exploitation plans:** For those that were intending to progress in their activities, most stated that they intended to enter in a licensing agreement with another organisation as part of their exploitation plans. This result was broadly similar for both successful and unsuccessful applicants. Two unsuccessful applicants also stated that they intended to sell the intellectual property that formed part of the project.

- **Manufacturing and marketing:** Finally, respondents were asked to report their plans for future manufacturing and marketing activities for their products. A slightly higher proportion of successful applicants anticipated that the product would be manufactured in the UK, in comparison to unsuccessful applicants (49 per cent compared with 37 per cent respectively). Almost 90 per cent reported that they had plans to commercialise the product on a global basis.
6.10 Early Evidence of Impact

A range of econometric analyses has been completed to explore the causal effects of the Biomedical Catalyst on some of the key outcomes of interest (i.e. effects that would not have occurred in the absence of the programme), including TRL levels, cumulative investment in the project to date, overall annual R&D spending, and employment at the time of the application, and levels of funding secured (technical details of these findings are set out in Annex D).

- **Propensity Score Matching:** As suggested in the passages above, there were systematic differences in the characteristics of applicants at the point they applied for a Biomedical Catalyst grant. A propensity score matching model (a kernel matching model) was deployed to balance the characteristics of successful and unsuccessful applicants at the point of application. The model controls for the age of the project, the TRL level of the applicant, the cumulative investment in the project to date, overall annual R&D spending, and employment at the time of the application, and levels of funding secured, product type, and firm/academic bids. Scores received through the project selection process were not included in this model because of the nature of the project selection process; successful applicants would not share similar scores to unsuccessful applicants. This has led to the creation of a ‘matched sample’ which has been used for the regressions described below.

- **OLS and Negative Binomial Regressions:** A set of regressions have been implemented to estimate the causal effects of the Biomedical Catalyst on the outcomes of interest. These models allow for the following:

  o **Selectivity:** Selection bias driven by self-selection into treatment (i.e. observed and unobserved characteristics of firms and academics motivating their application for Biomedical Catalyst funding) was addressed through the selection of unsuccessful applicants to serve as a counterfactual (i.e. both groups can be assumed to share these observed and unobserved characteristics). Selection bias driven by the project selection process was addressed through two mechanisms. Firstly, only projects that made it through the outline bid or EOI stage were included in the survey (and as such, both groups can be assumed to share those features required to reach the full application stage). Secondly, both the score received from MAC or DPFS panels, and the average score of the independent assessment (at the full application stage), were included as control variables in these regressions. This makes an assumption that any observed and unobserved characteristics of the applicant influencing the likelihood of their success are captured in the scores received.

  o **Time elapsed since the application:** A variable amount of time had elapsed since submission of the application across the sample of applicants surveyed, and it is anticipated that the outcomes observed might be linked to the amount of time that had elapsed (note, in these regressions, the Biomedical Catalyst has been assumed to have had no impact as yet on applications received in rounds 5 and 6, as following the pilot of the survey, it was clear that insufficient time had elapsed since the commencement of these projects for these metrics to show any visible change).

  o **Exponentially increasing cost and time:** The exponentially increasing cost and time to progress to the next TRL stage was anticipated to have some influence over the outcomes observed (i.e. it would take longer for applicants at higher baseline TRL stages to progress, regardless of whether they were successful in the application process). This was allowed for through the inclusion of the square of baseline TRL levels as a control variable.

- **Project progress:** The results indicate that the programme has had a significant and substantial impact in the acceleration of the projects forming the focus of Biomedical Catalyst applications. The estimates suggest that (on average) to date the Biomedical Catalyst has caused these projects to progress almost one TRL stage
further than they would have done otherwise. These effects are strongest for Late Stage awards and weaker for Early Stage awards, with no significant impacts found on technological progress for Feasibility Studies (though this may be due to the small number of Feasibility Studies in our sample). Breaking down the effect by time, the bulk of the impact was achieved after one year, with no significant further progress visible in our results in the following year. However, we consider this finding to be a function of the discrete scale we are using (i.e. an applicant would move up a TRL level if they began a Phase II trial, but would not move up again until they started a Phase III trial).

- **Project spending**: The estimates suggest that the provision of funding has had a significant impact on overall investment in the projects forming the focus of the Biomedical Catalyst applications (suggested the resources invested in the project are additional). The impact on spending grows in each year since the application, supporting our view that the lack of a ‘treatment effect’ in year two relates more strongly to the discrete nature of the TRL scale than a failure to progress further.

- **Applicant level impacts**: When looking at the findings at the level of the applicant, it was not possible to reject the hypotheses that the Biomedical Catalyst has had no impact on total R&D spending or R&D employment. The results also seem to indicate that the Biomedical Catalyst has had a negative impact (overall) on the levels of external funding raised following the notification of the award (this excludes any funding contingent on a Biomedical Catalyst award). This can be partly explained by the Medical Research Council funding rules preventing ‘double-funding’ of the project (i.e. academic applicants are prevented from seeking additional finance), and indeed this is confirmed by the results - the negative impacts are confined to the academic applicants, while no effect is observed amongst the firms.

- **Regression Discontinuity Design**: In addition, a set of RDD analyses were completed, comparing those that ‘just made it’ to those ‘just missed out,’ were completed to provide supplementary verification of the findings described above. In principle, these estimates will be more robust than those described above, though less generalisable (in the sense that they describe the causal effect of the programme on the marginal applicant, rather than the population of successful applicants). The results also pointed to a positive causal effect on project level expenditure (of a similar order of magnitude to the analyses described above), though it was not possible to reproduce the estimated effect in terms of accelerating projects through the TRL scale. However, in general, the estimated treatment effects were of the anticipated direction, and the low statistical power of the analyses (driven by the small number of observations) may have hindered the capacity of these models to identify the causal effects anticipated.

The implication of this is that the Biomedical Catalyst has produced its effects - so far - by diverting resources that would otherwise have been deployed in other areas rather than leveraging additional resources (i.e. applicants would have pursued alternative R&D projects). From the perspective of a Cost-Benefit Analysis, this implies that the main resource costs associated with the programme (from the perspective of society, rather than the Exchequer) to date are the costs incurred in the management and administration of the programme. Equally, there are no short term GVA impacts to date in the form of the wages of R&D workers. From a social welfare perspective, the central issue is how far the projects forming the focus of Biomedical Catalyst are more likely to produce the desired commercial and scientific impacts than the alternatives that applicants may have had ‘on the shelf’. Additionally, if the Biomedical Catalyst has also helped accelerate the progress of projects more rapidly than they otherwise would have done, then there may be further social welfare benefits. More consideration to the implications that will need to be investigated moving forwards are set out in the next section.

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56 RDD methods are highly demanding on sample sizes, and in implementation, some compromises were required, including estimating the regression analyses using a parametric specification (using all observations), rather than a narrow a bandwidth of observations in the vicinity of the threshold.

57 The undiscounted value of the project may be the same in such a case (unless acceleration leads to other benefits, such as first mover advantages), but the present value of the projects may differ owing to the different time profile of the relevant benefit streams.
6.11 Summary

- **Progress:** The projects funded through the Biomedical Catalyst have shown progress since notification of the award, with the proportion at the stage of conducting clinical trials doubling from 14 to 28 per cent and similar progression observed from exploratory stages to in-vitro and in-vivo experiments (or equivalents). The progress made was also more rapid than that observed amongst unsuccessful applicants (66 per cent of whom suggested they will proceed with the project in some form, though in many cases development work has been postponed, while 20 per cent reported they had taken their project forward without any changes). Firm led projects and feasibility awards saw the greatest rates of progress (and the fact that feasibility awards are only open to firm led projects partly explain the more rapid progress observed amongst firms), though few applicants were at the point at which they were able to launch a new product to market.

- **R&D activity relating to the project:** Successful applicants saw R&D expenditure relating to the project rise faster in absolute terms than unsuccessful applicants. However, R&D expenditure relating to the project rose faster in percentage terms amongst unsuccessful applicants. This is partly explained by the lower base at which unsuccessful applicants were starting: development costs incurred by unsuccessful applicants at the point of application were typically 35 per cent of those incurred by successful applicants.

- **Broader R&D activity:** Similar patterns were observed for total annual R&D expenditure, which rose at a slower rate than expenditure on the project forming the focus the Biomedical Catalyst application. This suggests that both groups of applicants have undergone a process of diverting resources away from other areas to focus on these projects. In addition, unsuccessful applicants saw no change in the overall number of R&D projects they were involved in (while there was a rise amongst successful applicants), with the evidence suggesting around 90 per cent had increased their focus on alternative projects. No substantial effects were observed in terms of increasing the translational focus of academic researchers: the survey suggested that academic applicants were primarily involved in translation research projects both before and after their application to the programme.

- **Funding:** Successful applicants had attracted higher levels of funding from private or public sources than unsuccessful applicants at the point of their application, and appear to have had greater success in securing additional funds following the award (though not necessarily in connection with the project). Successful firms in particular saw their total funding rise by around 53 per cent (or close to £1m on average) relative to 36 per cent amongst unsuccessful applicants. This was driven largely by venture capital investment (and to a lesser degree, investment by business angels).

- **Collaboration:** Although increasing collaboration between industry and academia is one of the Biomedical Catalyst’s objectives, the survey did not provide substantial evidence to suggest such an effect has been produced to date. Successful applicants were less likely to have collaborated with partners in the development of their projects prior to their application than unsuccessful applicants, and were no more likely to enter new collaborative relationships afterwards (either in relation to the project funded or on a broader basis). There was, however, a suggestion that the new collaborative relationships formed by successful applicants were potentially more productive. Additionally, it is possible that the application process produced impacts on collaboration observed amongst both successful and unsuccessful applicants.

- **Research output:** Successful applicants were less likely to have produced research outputs (in the form of conference papers, presentations of results at conferences or events, or journal articles) to disseminate their research than unsuccessful applicants. This could be indicative of commercial secrecy and an unwillingness to publish until patents have been registered. However, case study evidence also shows that delivery of the Biomedical Catalyst award may divert attention away from these other activities, that (academic) applicants are delaying the preparation of articles to seek publication in higher status journals, or that the nature of the research being funded is less amenable to this form of dissemination, or that there is less need to publicly demonstrate results to attract funding.
• **Turnover**: The turnover of successful firms (and commercial entities created by academic applicants or their institutions to exploit the intellectual property generated through the project, as reported by around 20 per cent of academic applicants) rose more rapidly than that of unsuccessful applicants (though for the majority, annual sales were zero at both the time of the application and the survey). It is difficult to link this result to Biomedical Catalyst funding, as so few had brought a product to market, though there were indications that some applicants had been able to secure licensing agreements which may be contributing to the changes observed.

• **Employment**: Total employment rose more rapidly amongst successful applicants than unsuccessful applicants, though at a similar order of magnitude as R&D employment. This suggests that any jobs created to date are likely to be associated with the implementation of R&D projects rather than production, and it is not anticipated that the Biomedical Catalyst will have had any wider effects on output (GVA) beyond the wages received by R&D staff, or productivity at this early stage (which aligns with prior expectations).

These gross outcomes are summarised in the table below:

**Table 6.1 – Gross Outcomes: Total Change Between Application and February 2015**

<table>
<thead>
<tr>
<th></th>
<th>Successful Applicants</th>
<th>Unsuccessful Applicants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Application</td>
<td>Feb 15</td>
</tr>
<tr>
<td><strong>Cumulative Project Expenditure (£m)</strong></td>
<td>141.0</td>
<td>205.0</td>
</tr>
<tr>
<td><strong>Annual R&amp;D expenditure (£m)</strong></td>
<td>100.0</td>
<td>112.0</td>
</tr>
<tr>
<td><strong>R&amp;D Employment</strong></td>
<td>740</td>
<td>920</td>
</tr>
<tr>
<td><strong>Overall Funding (£m)</strong></td>
<td>292.0</td>
<td>484.0</td>
</tr>
<tr>
<td><strong>Total employment</strong></td>
<td>930</td>
<td>1,170</td>
</tr>
<tr>
<td><strong>Total turnover (£m)</strong></td>
<td>71.0</td>
<td>88.5</td>
</tr>
</tbody>
</table>

Source: Ipsos MORI (2015), based on unweighted figures
7 Conclusions and Recommendations

This section sets out the main conclusions from this process and the interim impact evaluation of the Biomedical Catalyst programme. The conclusions are followed by a set of recommendations that might be considered in the design of future programmes (or modifications that may be helpful in future delivery).

7.1 Conclusions

7.1.1 Demand for the Biomedical Catalyst

The Biomedical Catalyst has seen high levels of demand over the course of the first six rounds of the competition, and Innovate UK and the Medical Research Council have faced no major challenges in committing funding at the levels foreseen. The high demand (at least amongst firms) may be reflective of recent changes in the structure of the life sciences industry, in which dis-investment by large pharmaceutical firms has been accompanied by rapid growth in the number of R&D intensive micro-businesses more dependent on equity than profits to fund their activities. There is little strong evidence to suggest that there has been a supply side response in financial markets to this growth in demand in the UK, suggesting a clear strategic requirement for the type of funding offered through the Biomedical Catalyst (though anecdotal evidence gathered from stakeholders suggests conditions began to improve in 2014, and there may be a case to consider re-focusing the scheme on those areas where funding constraints are strongest).

7.1.2 Marketing and Communications

These results indicate that the marketing activities employed by Innovate UK and the Medical Research Council have been largely effective in raising awareness across the communities of interest. For example, business demography statistics suggest that there are some 3,000 SMEs active in the life sciences sector (of which 2,000 were active in the medical devices sub-sector). Almost 800 expressions of interest to the programme have been received and, though it is not known how many of these involved duplicate applications, this suggests a high rate of penetration in the sector. High rates of penetration can be observed across the applications received by the Medical Research Council.

Some stakeholder concerns were raised, however, as to how far awareness had reached some sub-sectors of the industry (particularly the medical technology sector) and, while the profile of applications (skewed towards drug development projects) has broadly reflected the composition of the industry in terms of GVA, it was less representative of the number of active enterprises. However, from an economic perspective, consideration needs to be given as to how far this is consequential: supply of venture capital to medical technology development has remained consistently higher than for biotechnology and pharmaceuticals (possibly suggesting lower levels of need), while the high productivity differential between these sectors may suggest narrower scope for significant economic benefits to the UK. As regards digital health, there were suggestions that while awareness of the Biomedical Catalyst may have been low amongst those active in this emerging area with significant potential, the pipeline of investable projects was such that alternative types of instrument may be more suitable for addressing the types of challenge faced.

The evidence also suggested that while a strong brand has been built up in terms of awareness of the Biomedical Catalyst in the industry and amongst investors, and the DPFS amongst academics, awareness of the two routes through the programme was generally low. This may have limited the ability of applicants to decide how to optimally engage with the programme (either as lead applicants or as collaborators), as well as maximise its
effects on investor perceptions. It is likely that this is in part caused by the absence of a unifying communications platform for promoting the programme (though the evidence suggests that Innovate UK and the Medical Research Council have collaborated well in their efforts to raise awareness).

7.1.3 Project Selection

The high volume of applications received by the Biomedical Catalyst has allowed Innovate UK and the Medical Research Council to adopt a project selection process involving both a high degree of scientific scrutiny and high scientific standards of proposals put forward by applicants at both the DPFS and MAC panels. The balance of opinion was such that, by and large, the processes adopted in the delivery of the programme were highly effective in supporting these aims. In particular, the two main project selection panels were highly respected in their ability to identify scientific issues associated with project proposals, as was the selection of and feedback from peer reviewers approached by the Medical Research Council to scrutinise academic-led proposals.

A view was expressed that the panels are risk averse in the sense that they tend to favour projects that are underpinned by science that has been well tested (and this is reflected in the differing levels of resources invested by successful and unsuccessful applicants in the development of their projects prior to their applications). While such an approach is likely to minimise wasted resources in the form of projects that fail due to safety or efficacy reasons, it is possible that some applications with significant potential to deliver commercial or health benefits may fail to satisfy the high standards set by the panel. Scrutiny of additionality does not form a major focus of the project selection process. This may not necessarily have been an issue of material concern to date owing to weak supply of finance to the sector, though if (as asserted by stakeholders) conditions are improving, the risk that resources are allocated to ‘non-marginal’ projects (projects that would not have proceeded anyway) will likely increase (an issue of more central importance for firm-led applications).

There are some aspects of the delivery process that work against the aspirations for detailed scientific appraisal of project applications. A range of stakeholders (from panel members through to applicants) suggested that there was insufficient focus within the framework for Innovate UK application forms on the scientific case for the projects (focusing more on commercial and business planning issues), leading to difficulties in reaching an informed assessment of the scientific merits of the application on the basis of the paperwork supplied.

The study team understand that the assessment panel mechanism is used on a broad range of Innovate UK competitions. In other competitions, processes such as ‘Moderation panels’ are used to offer further scrutiny of applications that are on the ‘borderline of fundability’ after assessors have given feedback. However, the case of the Biomedical Catalyst requires a particularly scientifically rigorous technical add-on in the form of the MAC. In this specific context, questions can be raised over the added value of many of the independent assessments of applications received by Innovate UK (to which little resource has been devoted on a per application basis). While this process appears to have had a large screening effect at the expression of interest stages, in the full application stage the mechanism did not filter out a large proportion of Early or Late Stage applications, and is unlikely to have had a substantial effect on the final outcome of the project selection process. However, the variable scientific quality and depth of the feedback generated through assessments have not worked to streamline the deliberations and questioning of the MAC (evident in the low correlation between scores given by the MAC and the independent assessments at the full stage), while anchoring applicant expectations (leading to reputational issues where there is substantial divergence).
7.1.4  Project Delivery and Monitoring

The portfolio of projects funded is currently at an Early Stage of delivery, though there is no indication that there are substantial delivery risks at present (underspend is low across the Innovate UK portfolio, while risks associated with Medical Research Council projects are currently judged to be low).

However, the effectiveness of the two monitoring systems has strengths and weaknesses. Innovate UK monitoring officers tend to focus on the delivery of research, financial expenditure and progress towards commercialisation. They rely on the expertise of the Lead Technologists when any questions about the science arise but in line with Innovate UK’s remit the monitoring is end goal oriented rather than scientific milestone oriented. While this has led to an approach of monitoring that is viewed as pragmatic amongst applicants, it does introduce challenges for Innovate UK in identifying situations where resources might be most effectively withdrawn from projects early, for example, if initial results raise substantial concerns relating to toxicity or safety of the products being developed. While the standard monitoring processes monitor project progress on a quarterly basis, programme level monitoring of the outcomes achieved is limited to a project close-down report (with no interim or direct post-completion monitoring of results). The Medical Research Council has adopted a more scientifically rigorous approach for defining project milestones, allowing more rapid decision making where necessary and minimising wasted resources.

7.1.5  Technological Progress and Project Additionality

The survey results illustrate that successful applicants have progressed with their projects at a more rapid rate than unsuccessful applicants. Furthermore, the econometric analyses completed to date suggest that projects have progressed almost one TRL stage further that they would have done without Biomedical Catalyst funding. Additionally, the evidence gathered to date indicates that the programme has also levered in additional expenditure on the projects forming the focus of Biomedical Catalyst that would not have occurred anyway (suggesting that scheme is delivering against its aims to accelerate the projects concerned). This evidence would potentially allay concerns that the level of scientific scrutiny applied during the appraisal process is leading to the selection of those projects that would have otherwise been taken forward in the absence of Biomedical Catalyst (despite the evidence that issues relating to additionality are not given as rigorous scrutiny at this stage). However, while positive progress is being made by applicants, few projects have been completed, and the majority of projects remain a long way from market. As such, it is too early to judge how far the scheme will lead to its desired commercial and scientific results.

7.1.6  Broader Applicant-Level Impacts

Notwithstanding the evidence above, it is not possible to reject the hypothesis that the Biomedical Catalyst had no effect on the overall resources invested at this stage (measured either by R&D spending, or R&D workers employed) in any of the econometric analyses deployed. A possible interpretation of this finding is that the Biomedical Catalyst has encouraged applicants to divert resources to the projects forming the focus of their application to the programme and away from other R&D projects. This scenario finds some support from the broader survey findings: both firms and academic applicants reported that they were involved in a number of ongoing R&D projects at the time of their application, and a high proportion of unsuccessful applicants suggested that they had re-focused on alternatives following their rejection.

Such an interpretation has some important implications: firstly, it would imply that the main additional resource cost associated with the Biomedical Catalyst to date has been the management and administration costs incurred by Innovate UK and the Medical Research Council in their administration of the scheme (with public resources acting primarily to de-risk the project from the perspective of the applicant, at least as far as the firm led
applications are concerned). Equally, at this stage, the scheme is unlikely to have led to any short-term GVA impacts through the employment of additional R&D workers. Secondly, the net social welfare benefits of the Biomedical Catalyst will be dependent on the expected private and social returns on the project relative to the alternatives that have been displaced (and this cannot be judged until products have been launched to market).

Clearly, it is premature to implement a formal assessment of the cost-effectiveness of the scheme at this stage (and it was always anticipated that this report would serve as a baseline for the longer term impact evaluation). Little information is available on the characteristics of the alternative projects displaced by the programme, rendering any form of ex-ante (or probably ex-post) cost-benefit analysis of the scheme highly challenging. However, the research raises a range of important further issues or hypotheses which it will be important to explore as the projects move forward:

- **Early nature of results**: The survey of applicants reported above took place in February and March 2015. While the first competition round reached its conclusion in the summer 2012 (almost 3 years prior to the survey), the contracting and due diligence processes and other administrative aspects meant that defrayment of grant expenditure only began in earnest in 2013/14. As noted in section 4, only a small share of projects have reached their conclusion, the majority of which are Feasibility Studies at the earlier stages of technical development. As such, effects on R&D expenditure and employment may only become visible once (or if) applicants move up to additional stages in the development pathway (as projects progress through the development pathway, costs will increase at increasing rate).

- **CROs and CMOs**: A high share of project costs will be spent on the services provided by Contract Research Organisations and Contract Manufacturing Organisations. As described in the preceding sections, these expenditures may result in the main R&D employment effects being observed to a large extent outside of the applicant organisations concerned, although the survey evidence suggested that the project selection process has potentially helped to focus these expenditures in the UK. This will be explored in the next stages of the study through the data-linking exercise described below (though the failure to reject the hypothesis that Biomedical Catalyst has no statistically significant effect on R&D expenditure may imply challenges in finding causal effects).

- **Concentration of resources on riskier projects**: One possibility is that the Biomedical Catalyst has encouraged applicants to focus their efforts on projects with higher rates of private (and potentially social) returns, but where the outcomes are more uncertain. The high standard of scientific appraisal applied in the selection of the more costly Early and Late Stage awards can offer some assurance that the underlying rationale for the projects has its basis in well-tested principles, though again, such a possibility cannot be fully explored until such a point that it is feasible to establish the relative returns to investment.

- **Broader external constraints**: There is also a possibility that broader external constraints faced by applicants have been influential on the results observed. Firstly, as highlighted in section 3, the supply of venture capital to the pharmaceutical and biotechnology industries in particular has been constrained, and this may have inhibited successful and unsuccessful firms alike in their efforts to secure additional funding. However, applicant firms in particular may have used the Biomedical Catalyst to delay the need for equity investment (possibly to increase the value of their capital assets or avoid loss of control). This may delay impacts on these measures.

- **Sample sizes and measurement error**: Finally, the samples available for the analysis have been relatively limited (while the data gathered for the analysis was through primary survey research, which may be associated with a degree of inaccuracy given the self-reported nature of the data). As the study moves forward, these constraints will ease. In the short-term, implementation of analyses based on administrative data will enable the focus to be broadened to the full population of grant applicants (and outcomes will potentially
be more reliably measured). Secondly, longitudinal primary research will be extended to applicants to rounds 7 and 8, helping to increase the availability of observations.

Additionally, over the next phases of the study, it is anticipated that applicants will begin to launch products to market. Consideration of how human health effects and any offsetting displacement effects in the product market might best be modelled will be a key focus of methodological development. Wider social outcomes and spill-over effects will be also examined.

### 7.1.7 Collaboration

The evidence gathered suggests that while programme delivery processes are highly supportive of collaboration between industry and academia, the programme itself has not led to the formation of new collaborative relationships to any significant degree (and the survey of applicants tends to suggest that successful applicants are less collaborative than unsuccessful applicants). This might in part be explained by the more passive nature of the mechanisms employed to promote collaboration (creating financial incentives, rather than actively fostering links between partners). Questions might be raised as to the importance of this objective to the successful delivery of the Biomedical Catalyst: the strength of the project appraisal is such that if there are any weaknesses in the skills of the team proposed the application will likely be declined (though there may be scenarios where the applicants’ failure to recognise a skills gap or fill that gap with external expertise have led to otherwise high quality proposals being failed).

### 7.2 Recommendations

In considering the future development of the programme (or any successor programme) it may be helpful to consider the following:

- **Marketing and communications**: There is a need for the Medical Research Council and Innovate UK to collaborate to develop a comprehensive marketing strategy for any future rounds of the programme. The design of this will need to consider:

  - Scope to further consider how best to market the scheme to the broader biomedical community including med-tech communities and emerging areas including digital health.

  - Opportunities to better develop and leverage the brand of the Biomedical Catalyst and highlight its rigorous approach to selecting the best translational R&D projects. This could help the programme to reach a broader audience, including the investment community in the life sciences sector. This funding stream has a number of unique attributes in the landscape of public R&D funding – its openness to a very broad range of applications; grants are large, available to private companies and are non-diluting (i.e. they do not require an equity stake). These strengths could be better leveraged to create a brand that can reach beyond the biomed sub-sector to a broader range of health sector communities. A focus on a single brand could also help to communicate the twin funding track nature of the Biomedical Catalyst (academic and firm) which could potentially help to support joint working between these two communities.

  - Notwithstanding a high number of participating universities, the programme could consider alternative channels to raise awareness about participating (mainly in a role of a partner) in the Biomedical Catalyst programme. This is especially the case for reaching audiences beyond the established Medical Research Council-funded higher education institutions with strong technical research fields. This channel would be
designed to communicate the opportunities to become a collaborating partner in a biomedical project to engineers with innovative ideas that have a potential application in improving wellbeing and health.

- **Application process:** It may help to improve the quality of the assessment of applications from firms if the guidance associated with the Innovate UK application form is strengthened to stress the importance of including a scientific annex offering further detail on any science which they consider to be new and innovative within their application. Additionally, guidance to applicants on the following could be beneficial:
  - The probability of success of applications at the MAC — explaining what proportion of applications succeed at MAC stage and the extent to which positive assessor scores are a good predictor of a successful funding outcome (while recognising that success rates can vary substantially from round to round depending on the quality of proposals received). This recommendation has already been actioned by Innovate UK in the design of the round eight of the scheme, which took place outside of the window of the research for this study.
  - The likely focus of the discussion — drawing on the experience of previous meetings of the MAC and offering guidance around the likelihood of applications receiving detailed scrutiny on the science underpinning their proposed research and the likely focus on clinical issues. Innovate UK could also help applicants to better prepare for the MAC by offering clearer guidance around what can be expected here and the importance of being ready to respond to questions of a detailed clinical nature.

- **Assessment process:** It is recommended that Innovate UK consider how to develop the independent assessment of Biomedical Catalyst applications, which currently do not add substantial value to the full stage application project selection process but do cause reputational issues for the programme. The study team recognise however that change may be difficult to secure in the short term owing to harmonisation of some processes across Innovate UK and the complementary IT infrastructure. Additionally, it is also acknowledged that Innovate UK is seeking to strengthen the pool of registered assessors (and the Medical Research Council has indicated that it is in a position to further assist with this process) to improve the depth and breadth of expertise that can be applied.

- **Additionality:** Guidance could be provided to panel members to more strongly and clearly focus their attention on issues of commercial impact and additionality. This is likely to be become increasingly important if financial conditions continue to improve. For both MAC and DPFS panels there is also scope to ensure that the key question of ‘would this project be funded by other means?’ is at the forefront of member’s minds when scoring projects to encourage a greater focus on those proposals with less certainty regarding the underpinning science or the likelihood of regulatory approval, though with high potential social and private returns, that may be less likely to be taken forward by the market in the absence of public sector support.

- **Flexibility:** In cases where the MAC feel that the science behind an application has not been adequately tested, it may be challenging to change rules for the MAC to offer an alternative awards (such as feasibility awards) to fund the initial testing needed (in the interests of fairness to all applicants). There may scope for the panel to have the option to offer the applicant an award with conditional milestones relating to any initial testing work that is viewed as missing, that would unlock further funding should these conditions be met, and committed funds recycled into later competition rounds if not. This would be appropriate in cases where the ideas for the project are seen as innovative, the commercial potential as strong and there is a clear reason why the project could not secure funding through an alternative route. However, it may require applicants to re-profile projects if the proposed initial steps do not align with areas deemed in most need of further testing. An alternative approach suggested by one stakeholder would be to reduce the size of Early Stage awards and not
require that they secure approval from the MAC. The acceptability of that approach would rely on an improved perception amongst the programme secretariat panel members of the performance of Innovate UK assessors.

- **Monitoring:** The differences between the Medical Research Council and Innovate UK processes partly reflect differences in the organisations’ focus and their key audiences. Despite having a systematic approach where the monitoring officers flag any issues to the Lead Technologist, there may be scope nevertheless to incorporate additional scrutiny of scientific progress into Innovate UK processes, which might be best achieved through pooling of expertise (such scientific monitoring will likely require specialist domain relevant expertise that cannot necessarily be supplied by Innovate UK monitoring officers).
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