

# WORKING P A P E R

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## Project Retrosight

### Research Pack

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# Preface

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The purpose of this document is to provide an overview of Project Retrosight, a study of the translation of basic and early clinical biomedical research into clinical practice in four countries over a 10-20 year period. The document also provides a description of the research process for the study, with illustrative examples and resources such as protocols to assist researchers and provide guidance through the research and reporting process. The intended audiences are the participating funders and the in-country study teams who will be conducting case studies for Retrosight.

The discussion provides insights into how issues were resolved or decisions made in developing the framework or conducting certain cases. In doing so, the research pack does not attempt to provide comprehensive prescriptions or instructions for participating research teams. It is intended to generate further discussion to be pursued at the workshop on 27-28 February.

The research is jointly funded by the UK Department of Health; the Heart and Stroke Foundation of Canada; the National Heart Foundation of Australia; the National Heart Foundation of New Zealand; and the Health Research Council of New Zealand.

RAND Europe is an independent not-for-profit think tank and research organisation that serves the public interest by providing evidence for policy making and public debate. HERG, a Specialist Research Institute of Brunel University, has focused, as one of its main research themes, on methodological and empirical studies of the impact of research, principally in the field of health. For more information about RAND Europe or this document, please contact Steve Wooding or Jennifer Rubin at:

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# Abbreviations

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Arc Arthritis Research Campaign

AHP Allied health professionals

HERG Health Economics Research Group

HSR Heart and Stroke Research

NICE National Institute for Clinical Excellence

PI Principal Investigator

RE RAND Europe



### Introduction to the Research Pack

This chapter begins with a brief description of Project Retrosight. It then goes on to explain the approach, the evaluation framework, adopted for the project. Chapter 2 then provides a discussion and overview of case study selection. The third chapter outlines the case study protocol; and data collection methods for the case studies including the use of document reviews, key informant interviews and bibliometrics. Chapter 3 also provides an overview of the reporting of case studies. Finally, Chapter 4 briefly describes the analysis of case studies in order to draw out conclusions and recommendations. The annexes provide more detail on the categories of the Payback Framework, approach letters and protocols for the conduct of case studies, approach letters and protocols for the conduct of interviews, and an outline of the reporting process for individual case studies.

### Introduction to Project Retrosight

As those of you participating in the project already know, Project Retrosight is a three-year multinational study using a framework developed by the RAND Europe/HERG team, the Payback Framework, to investigate the impact of biomedical research, including how basic and early clinical biomedical research is translated into clinical practice and ultimately how it effects health. It may be useful to delineate in more detail for those new to the project the aims and structure of the project and of the payback framework.

Specifically the project aims to:

- Undertake a study of the payback from cardiovascular research in four countries, taking research that was carried out 10-20 years ago as a starting point
- Investigate the comparative strengths and weaknesses of different ways of funding research

Governments and charities aim to improve health and well being through spending on medical research. Although there is general agreement that improved knowledge and understanding will lead to such improvements, there is little understanding of how this occurs. As the emphasis on evidence based policy increases, and following a general increase in funding for basic research, it is important to be able to justify research spending with an understanding of how it improves health. An understanding of this translation process may also allow research funds to be allocated more effectively and research findings to be translated more efficiently.

The impacts of biomedical research occur over long time-scales and may take tortuous routes. Project Retrosight will comprise a series of over thirty case studies of research groups working in cardiovascular research in Australia, Britain, Canada and New Zealand; tracing the development of their research over 10-20 years. We will examine a mix of basic research and clinical or more applied research. Each case study will develop a history of how the research emerging from the group has made an impact up to the present day. The history will also include the research group's composition and key previous work. Each case study will be written up in a standard template to allow comparative analysis. To facilitate this analysis we will 'collapse the complexity' of the case studies by scoring them on a number of indicators at a workshop with experts in the field for each country. We will then undertake detailed analysis of the qualitative data (case studies) and the quantitative data (scores).

Using this evidence base we will carry out a detailed assessment of how basic research is translated into clinical practice, drawing out policy observations and recommendations that will be of use to biomedical research funders. In addition, we will then be in a position to provide a detailed catalogue of the paybacks from the research. The scale of the study should enable us to make a major contribution to understanding of the way the results of basic or early clinical research eventually translate into application, providing invaluable information for policy makers within health R&D.

## Introduction to the framework

The framework that is applied in Project Retrosight was developed by RAND Europe and HERG. The model described here is from an adaptation of the evaluation criteria and a logic model developed by the Health Economics Research Group at Brunel University to assess the "payback" of health services and biomedical research. This work was commissioned originally by the Department of Health in 1993 to evaluate the health service research that it supported. Subsequently the payback framework has gone through

a number of iterations and applications. The first phase of the work, described in Buxton and Hanney (1994, 1996) and Buxton and others (1994), consisted of:

- a categorisation of payback under five headings: knowledge, research benefits, political and administrative benefits, health sector benefits and broader economic benefits (as illustrated in Box 1.1);
- the development of a nine-step model consisting of seven stages and two interfaces showing how, and at what stages, categories of payback could be assessed (as illustrated in Figure 1.1); and
- the testing of the categorisation and modelling in eight case studies.

Questions arose about the social and political environment and about the linearity of the process depicted. Having engaged with the issues raised by these questions, the final version was presented in Hanney, Gonzalez-Bock and others (2003).

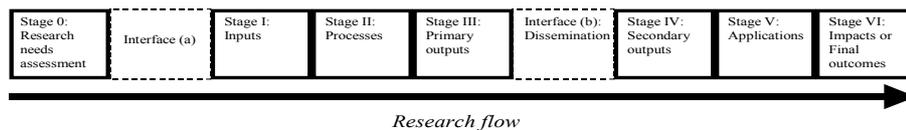
A.	Knowledge
B.	Benefits to future research and research use: <ol style="list-style-type: none"> <li>i. better targeting of future research;</li> <li>ii. development of research skills, personnel and overall research capacity;</li> <li>iii. critical capability to utilise appropriately existing research, including that from overseas;</li> <li>iv. staff development and educational benefits.</li> </ol>
C.	Political and administrative benefits: <ol style="list-style-type: none"> <li>i. improved information bases on which to take political and executive decisions;</li> <li>ii. other political benefits from undertaking research.</li> </ol>
D.	Health sector benefits: <ol style="list-style-type: none"> <li>i. cost reduction in the delivery of existing services;</li> <li>ii. qualitative improvements in the process of service delivery;</li> <li>iii. increased effectiveness of services, eg increased health;</li> <li>iv. equity, eg improved allocation of resources at an area level, better targeting and accessibility;</li> <li>v. revenues gained from intellectual property rights.</li> </ol>
E.	Broader economic benefits: <ol style="list-style-type: none"> <li>i. wider economic benefits from commercial exploitation of innovations arising from R&amp;D;</li> <li>ii. economic benefits from a healthy workforce and reduction in working days lost.</li> </ol>

(SOURCE: Buxton and Hanney 1994, 1996, 1997)

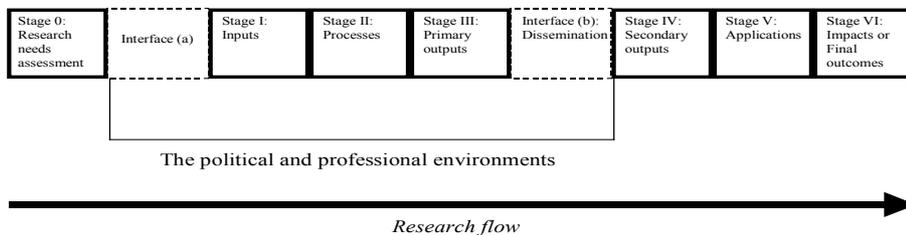
Box 1.1: Payback categories

From this basis, the payback framework has been applied to a number of different contexts. For example, Buxton and Schneider (1999) explored the possible application of this to a Canadian research organisation that funded basic biomedical and early clinical studies alongside health services research. Buxton and others (2000), developed a postal questionnaire based on the payback categorisation and model to be applied to the (then) National Health Service’s North Thames Research and Development Programme. This approach was developed further in Croxson and others (2001), which examined how a system of monitoring could be developed. The model has informed an analysis of health research systems on behalf of the World Health Organisation (Hanney, Gonzalez-Block and others 2003; Pang and others 2003). In relation to health services research it has most recently been used in assessments of the payback from Health Technology Assessment programmes in the UK and the Netherlands.

**Basic model**



**The political and professional environments**



**Forward leaps and feedback loops**

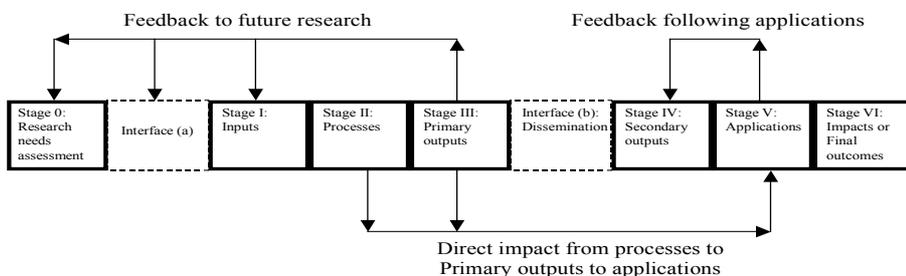


Figure 1.1: Genesis and development of the payback model

Recently we also applied this framework to a study for the Economic and Social Research Council to see whether and how it could be transferred to the evaluation of the payback from social science research. We found this to be a success, and found that some of the findings from the application of the Payback Framework to social science read back across to science and medical research. For example, in some cases there may be sensitivity about revealing research findings and about attributing information to participants in the research. This finding has informed our thinking about the nature of consent for Retrosight, as well as raised a methodological point about whether some impacts are difficult to get at through this method. Also, participants preferred to be rung up and talked through protocols than to work through a survey on their own.

Most relevant for Retrosight have been two projects jointly conducted by UK team members to apply the payback framework to assess the impact of basic and clinical research. The first project examined the impact of a body of diabetes research conducted some 20 years earlier by a leading UK research team (Hanney, Frame and others 2006). The second evaluated the outcomes and outputs of the research funded some 10-14 years earlier by the UK's Arthritis Research Campaign (arc) (Wooding, Hanney and others 2005). The following section describes the evaluation framework.

## Evaluation framework

The evaluation framework is made up of two components. The first component is the classification system for the outputs and outcomes of research. It should be emphasised that the classification system is designed to cope with both quantitative (eg the number of research publications) and qualitative (eg a description of career progression following the awarding of a research grant) outcomes and impacts or measures. The second component is a logic model of the research process. Logic models are widely used in evaluation methodology to understand input–process–output relationships and to break down research programmes into their constituent parts (WK Kellogg Foundation 2001).

## Payback categories

The multidimensional category of payback provides the classification system for the outputs and outcomes from research funding. Below each category is briefly described. For a more comprehensive discussion of the categories see Annex A.

### Knowledge production

The knowledge produced by research is the first output and is often contained in various publications and patent applications. Quantity, quality and impact are all relevant in the measurement of knowledge produced. One way of assessing knowledge production is through bibliometric data and citations. Peer review and editorial comment in systematic literature review may be useful indicators of quality. Impact factor for journals (associated with citation), or dissemination through high readership are useful impact measures.

### Research targeting and capacity building

The better targeting of future research is frequently a key benefit from research, especially from research that is more basic and/or methodologically oriented. Where follow-on research is clearly associated with the original research, it can be useful to obtain information on the source and amount of such funding. Medical charities can play a key role in funding research in a specific field that opens up questions or issues that then attract further funding from more general research funders, such as the UK Medical Research Council (MRC) and the Wellcome Trust. Further outcomes include new methods, assays and diagnostic tools.

Measures of research training used in previous studies include number and level of higher or research degrees or other career development resulting from the research funding (Mushkin 1979; Verhorn and others 1982).

### Informing broad policy and product development

This category involves looking at the policy, broadly defined, or products, from which the health and economic benefits accrue. For example, research can be used to inform policymaking in a wide range of circumstances including government national policies, policies made by managers at many levels within a health service, policies agreed at the national or local level by groups of health care practitioners in the form of clinical or local guidelines; and policies developed by those responsible for training, education or inspection in various bodies (Hanney, Soper and others 2003).

Basic research is less likely than that from clinical researchers or allied health professionals (AHPs) to be used to inform policy. However, research can also be used to inform product development. There generally has to be some degree of informing policies and/or product development as a necessary step to further outcomes. In this respect informing broad policy and product development are conceptually similar.

### Health benefits

These benefits might be viewed as the “real” payback or outcomes from health research. Greater clinical effectiveness resulting from research-informed drugs or procedures will lead to increased health. Various measures of health gain do exist, for example the use of Quality Adjusted Life Years (QALYs).

This category is wider than health gain, and some aspects can be seen as benefits to the health sector more generally. For example, cost savings in the provision of health care may result from research-informed changes in the organisation of services, or in the particular therapies that are delivered. It might be necessary to consider whether potential savings have been realised in practice – either as cash savings or the release of resources for other valuable uses (Hanney *et al* 2005). Further, it is important to be aware of possible displacement effects whereby costs are being transferred elsewhere. Improvements could arise also in the process of health care delivery; these could be measured by techniques such as patient satisfaction surveys.

### Broader economic benefits

A range of benefits can accrue to the national economy from the commercial exploitation of research. These could include employment and profits resulting from the manufacture

and sale of drugs and devices (Rosenberg 2002) and exports and/or import substitution (Gadelha 2000; Hale and Towse 1995). Although it is important to avoid double counting, it may also be valuable to adopt a human capital approach focusing on the value of production that is gained from having a healthy workforce. This can be measured by examining the reduction in days off work. Typically, a human capital approach has been used, in which potential future earnings are calculated for people who, as a result of advances in medical research, can continue to contribute to national production (Drummond and others 1992; Mushkin 1979; Weisbrod 1983). However, this type of measurement may lead to inequities in funding of health research, especially in favour of research that is relevant for those of working age. An additional concern is the value of production lost from days off work which may be overestimated if it is measured in terms of relevant wage-rates (Koopmanschap and others 1995).

## Payback model

The second element of the evaluation framework is the logic model. Its various stages are shown in Figure 1.2 of the arc model. The linearity of the model serves to indicate a series of assessment stages and does not claim to represent exactly how the research translation process necessarily, or usually, works. Particularly in relation to more basic research, the initial flows of outputs from the research are into the pool or stock of knowledge and from there back to further research. While it is not completely possible to tie the categories of benefits to certain stages of the model, it is possible to identify broad correlations: the *knowledge production* and *research targeting and capacity building* categories together are generally the primary outputs from research; the *informing policy and product development* category relates to the secondary outputs; and the categories *health and health sector benefits* and *broader economic benefits* respectively are generally the final outcomes. Hence, although each category of output should be assessed for each stage of the model, certain stages tend to produce certain outputs.

### Stage 0: topic/issue identification

This stage involves the generation of the original ideas for the research and varies considerably, depending on whether the main driving force is generated internally by the researcher or generated externally. For many researchers the topics will be curiosity-driven and based on the researchers' examination of the existing stock or pool of knowledge and opinions about where gaps and/or opportunities exist, and where further research could advance understanding. Such factors will also inform clinical researchers but here, consideration of clinical needs could be a factor and might be based on personal experience of treating patients.

Where research topics are generated externally, the identification of the issue comes from a process of needs assessment that could involve analysis either within the scientific community or more widely. In the latter case, many groups could be involved, including not only members of the wider research community and representatives of research funding bodies, but also potential users and beneficiaries of the research that are drawn from some combination of the wider political, professional, industrial and societal environment.

**Interface A: peer review**

The nature of the activities at Interface A will vary depending on the type of issue identification. Where the issues are generated by researchers, the interface traditionally involves processes whereby the researcher develops a detailed proposal and submits it for peer review. In fact, there is not really much of an interaction between researchers and the wider environment in this case as often, peers are required to assess on the quality of the science (although the issues of relevance and impact may be influential also). Where the topics are generated outside the research group, the interface issues become more important as there are potential difficulties in ensuring that the research community is actively engaged with the priorities that have been identified, and that the project specification meets the needs as identified. In both cases, however, there are issues about how far the proposal was subject to changes as a result of the review process.

**Stage 1: inputs to research**

It is important to consider the financial inputs, including any beyond the field-specific funding, the expertise of the research team, the knowledge base on which they have built and the availability of techniques, reagents and equipment. The idea behind examining other funding brought in to support ongoing cardiovascular research is to look at whether the initial funding helped to increase the funding of cardiovascular research by general funders of health research.

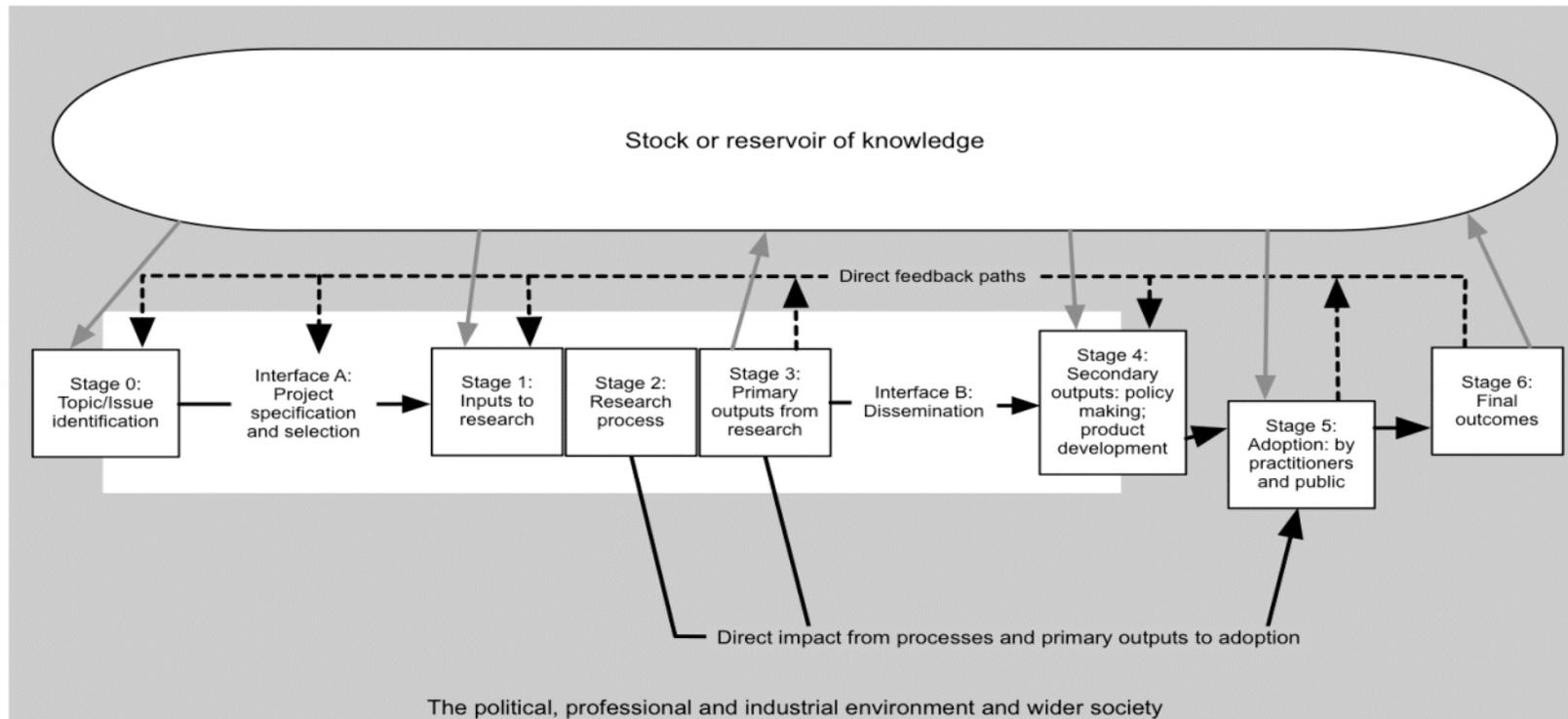
**Stage 2: process**

Consideration should be given to how appropriate the proposed methods turned out to be, and whether any difficulties were encountered. In some cases it could be relevant to explore how far potential users were involved at this stage. It is possible that the difficulties identified at this stage could explain later problems with translation or uptake of the research findings.

**Stage 3: primary outputs**

Knowledge production as represented by the various types of publications is a major primary output from the research. Most of the primary outputs will feed into the stock of knowledge and become part of the body of knowledge that informs further research or is incorporated into systematic reviews. The research benefits in terms of targeting future research and capacity building can be seen as featuring here also, but they represent either feedback to further research that is conducted by team members, or findings that feed into the stock of knowledge and help target future research. Further, we may consider how far the career development that is based on cardiovascular funding helps to propel some researchers into positions within the health care system, where they can play a role in ensuring that the later stages of translating research findings into outcomes are achieved.

Figure 1.2: Payback model (source: Hanney, Wooding and others 2004)





### **Interface B: dissemination**

Usually, dissemination is seen as being somewhat more active than the mere production of academic publications. However, there are clear overlaps between activities, and sometimes it is possible to record not only dissemination activities but also the successful transfer of research findings to potential users in the political, industrial and professional environment and wider society. Presentations to user groups and media activities are major ways of disseminating findings, as is the production of brief summaries of findings which are targeted at specific user groups. In previous case studies examining applied research attention has focused also on the way in which some researchers conduct study days or training that is based on the approach developed by their research: and these have been found to be highly effective dissemination mechanisms.

### **Stage 4: secondary outputs**

A wide range of items can be considered to be secondary outputs. In terms of policies, the key issue is that policymaking involves those in positions of authority making choices that have a special status within the group to which they apply. The results can take many forms, ranging from national health policies made by the Government to clinical guidelines determined by professional groups, to guidelines or care pathways, etc. that are agreed within local units. Clinical guidelines provide a particularly fruitful form of secondary output on which to focus analysis (Grant and others 2000). As noted above, many other items can be included also if they are informed by research findings, for example, “how-to” manuals, criteria adopted by evaluative or inspectorial bodies, training packages and official curricula, legal decisions and media campaigns by health care providers. Where the research seems to have resulted in secondary outputs, it is useful to explore the factors that have led to this.

The position of systematic reviews is more complex. They are themselves a form of research and their production and dissemination can be considered using this framework, but inclusion of a study in a systematic review is a form of secondary output and might lead on to further use.

In relation to product development, it is important to distinguish between the commercialisation of a proven approach (which is a secondary output) and consideration by a drug company of therapeutic potential or novel mechanisms (which is a primary output). For example, if research findings are directly built upon in the process of developing a commercial product, such as a new drug that is licensed for arthritis, this can be seen as an important secondary output.

### **Stage 5: adoption**

Behavioural change by practitioners and/or the public is necessary for the research findings incorporated into secondary outputs to result in final outcomes. This may involve take-up of new drugs or procedures as set out in a secondary output such as (in the UK) a guideline from the National Institute for Clinical Excellence (NICE). Sometimes the adoption comes as a direct result of the primary outputs, as when clinicians decide to implement research findings even prior to the development of clinical guidelines. Either way, it is important to try to establish the adoption or take-up rates and to explore how far the behavioural change can be attributed to the specific research

findings, as opposed to other factors such as a more general change in climate of opinion in relation to, for example, the importance of exercise.

The role of the public in responding to informed advice – which is often research-based – is seen as increasingly important (Leong and Fuller-Ziegler 2004). Various factors can be explored here, including the extent to which patient behaviour might change as a result of interactions with health care providers who promote research-based messages, and how far the public might respond directly to publicity about research findings when they are used: for example, in media campaigns encouraging participation in preventative activities.

#### **Stage 6: final outcomes**

The final outcomes are the health and broader economic benefits identified in categories D and E in Box 2.1. Increasingly, these are seen as being the ultimate goal of health research funding, but estimating them in practice often remains difficult. At one level there might be data such as audit figures available from areas where there is known to have been local implementation of the research findings. At an overall level it is possible that figures may be available for the potential population who could benefit from the new drug or procedure and information about the level of benefit that a patient might receive. If knowledge about adoption levels is also taken into consideration, it might be possible to indicate the levels of benefit.

## CHAPTER 2 Case studies and selection

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### Introduction

There is a long history of applying a case study approach to examine the translation of research (Yin and Moore 1988). A case study approach has been recommended where the emphasis of a study is on showing the long-term benefits from health research (Lavis *et al* 2003). In the case of this project, the use of case studies enables narratives to be told with the aim of illuminating examples of how research funded in the early 1990s was translated (or not) into practice. Thus, each case potentially provides an illustration of long-term outcomes. Case studies are especially useful in illuminating research translation because they allow exploration of contextual and individual factors that are (or are expected to be) significant, and that are not easily captured by macro level analysis.

For these illustrative uses the case studies do not necessarily need to be representative of the wider research carried out at the time, but case studies of each type of research of interest should be included. For example, to explore the wider impacts of both basic and clinical research it is important to choose case studies of each type. The idea is to demonstrate the existence of routes of translation and instances of impact, showing how research can affect healthcare and wider society. For this type of work the selection of cases is, therefore, often purposive. There are good precedents for this approach to case study selection. For the case studies that have been conducted using the Payback Framework, given that one aim of the Payback research is to illuminate long-term outcomes, we have often focused on studies where it was judged that there was a reasonable chance of the research under investigation producing a range of research paybacks.

The second use for case studies is in trying to understand typical behaviour. In this case to provide insights into the research translation process that can be applied to improve the management and funding of research. In this case it is important that the conclusions from the case studies can be widely applied. For survey based studies this wide applicability could be achieved, and quantified, by ensuring the sample was statistically representative of the population. In case study research it is rarely possible to carry out enough studies to achieve what would commonly be considered statistical representative findings. Instead an analogy can be drawn with experimental repetition; when a finding is seen in three or four case studies it can be more confidently generalised than one that is found in only one or two examples. In order to increase the power of such comparisons

the cases on either side of the comparison may be select to balance other characteristics – so in a comparison of the effect of gender, comparison cases might be matched for the career position of the investigator.

The use of multiple cases allows insights and comparisons across several dimensions. In a study adopting a multi-case approach such as Project Retrosight, the aim is to ensure that the benefits from a range of modes of funding and types of research can be illustrated, and that there is scope for some generalisable cross-case analysis. One way to achieve this is to use a stratified random sample, and we recently used this approach to select case studies for a payback analysis carried out for the UK Health Technology Assessment programme.

Selection of case studies entails engaging with competing requirements. For example, there is a need for sufficient time to have elapsed that the research outputs could have been translated. On the other hand, evidence is needed – both from archival material and interviews – that would not be biased by the difficulty of recalling work that was undertaken some time ago. These selection issues are discussed in more detail below.

## Selection

Selecting a suitable set of case studies is critical to the robustness and validity of the research findings. In order to provide this we need compromise between international consistency and national discretion. One key aspect of the project is the opportunity to explore differences in national context – hence comparability between research examined in different countries is useful. This suggests that it would be helpful to seek case studies in the same subfields from different countries. This comparability need not be absolute but is a matter of extent e.g. six case studies from each country could be selected according to a prescribed list of subfields, remaining case studies could come from other subfields.

For Project Retrosight case study selection also incorporates a trade-off between risk of biases in the cases selected, and the risk of ending up with case studies where few outcomes had occurred or where lack of cooperation or other complication impedes the possibility of conducting the case study.

In order to engage these competing requirements, for Retrosight there are three main stages to case study selection:

1. generating a selection matrix to ensure that case studies are selected which reflect the variety of funding;
2. populating this matrix with suitable grants; and
3. selecting individual grants from this matrix.

In more detail, we suggest a system based on what we learned from work on the long term outcomes of Arthritis research. Figure 1 provides an illustration of this process.

In more detail the selection process would be:

1. A long list of possible grants/researchers is generated from funders' records and bibliometric analysis.
2. This list is tested against a number of eligibility criteria.
3. A short list of grants is produced which meet the eligibility criteria.
4. The individual funders then have the opportunity to exclude researchers or grants which they feel are unsuitable, providing reasons for those exclusions. Exclusions might be because a researcher is known to be unavailable or likely to be unco-operative with the project.
5. This produces a weeded short list
6. The final selection of case studies is carried out by the RAND/HERG team – this allows us to balance case study selection to allow the maximum comparative power of the case study design. At this stage additional country specific criteria – such as regional spread – would be taken into account.
7. This final selection would produce a final list of candidate case studies, and a list of reserves in case particular researchers are unwilling, or unable, to take part.

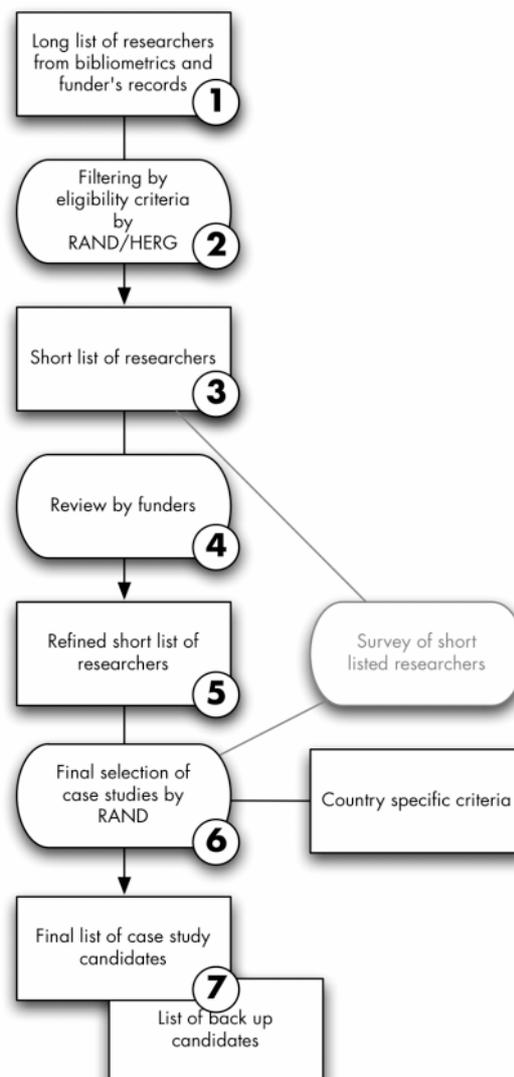


Figure 1: The proposed case study selection process

## Eligibility criteria

There are a number of possible eligibility criteria delineated for selecting case studies, as noted in the flow chart of proposed case study selection above. Only case studies meeting these criteria are short-listed. However, because of differences in how long lists are being assembled in different countries, for some criteria (such as time period) grants not meeting that criterion might not even be on the long list. These eligibility criteria will be discussed at the workshop 27-28 February. However, some of the criteria to include are: time period (the research grant must have started during 1989-1993); the grant will have been funded by an eligible funder; the Lead Researcher will still be publishing or only recently have retired (this is a pragmatic judgement based on the fact that we will need easy access to information on how the research has developed).<sup>1</sup>

## Selection Criteria

These criteria should be those which the study is most interested in researching. They are the primary criteria on which RAND/HERG would select the final list of case studies from the weeded short list and which we would investigate in more detail through the case studies. This is currently a prioritised list, so the order is important, as we are only likely to be able to select on four or five of them.

These selection criteria may include: type of research of project (Basic, Clinical, HSR). This is a somewhat complex criteria, relating as it does to the type of project and not just the researcher. need definitions of the alternative types of research. One possibility is to use the Frascati Manual definitions, however, these may not pick up the distinction between Basic and Clinical research as seen in a medical research funding context.<sup>2</sup> An alternative would be to use a system from one of the funders or to devise a system based around an idea that is popular in the UK Department of Health – the idea that clinical research involves ‘shaking hands with a patient’ – either as a research subject or to obtain

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<sup>1</sup> However, in practice this will exclude those who have moved out of science but into science related environments – e.g. science policy or health policy.

<sup>2</sup> The Frascati definitions are **basic research** is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view; **applied research** is also original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective; and **experimental development** is systematic work drawing on existing knowledge gained from research and practical experience that is directed to producing new materials, products or devices; to installing new processes, systems or services; or to improving substantially those already produced or installed.

samples on which the research is carried out.<sup>3</sup> Further possible criteria include breadth of experience of working across the spectrum from basic research to clinical practice; existence of soft/core funding that the PI could allocate at their discretion; multi-disciplinary/trans-disciplinary team; funding mode if there is comparability between the funding mechanisms of different country funders,<sup>4</sup> and how many different sources of funding the PI had.

### Factors to control for

There are a number of factors which, although we are not seeking to investigate them, it is likely to be important to try and control for in other comparisons. Where possible these would be borne in mind during case study selection and may include field of research; academic age; gender – selection should be representative of the situation at the time (i.e. if 25% of awardees were women we should aim for 25% of case studies with female PIs). Although we will control for this we do not intend to try and investigate the effects of gender on wider impact and translation.

It is also possible to examine the importance and influence of factors that we do not use as selection criteria. However, the study will not have been set up to allow powerful comparisons based on these factors. We have identified a number of these factors, often ones where there is no standard hypothesis to test, but where a deeper understanding of the issue could be important. These include, for example, amount of money required – there may be a critical mass; research group culture; early indicators of effective translation; curiosity driven versus mission directed (as far as we are aware the research funded by the funders would not allow this comparison, as the vast majority of research funded was purely curiosity driven); institutional setting; the location in which the research is carried out; international collaboration: the degree and types of international collaboration by the groups; the relationship between bibliometric and wider impacts

### Generating a selection matrix in the arthritis research campaign (arc) project

In illustration of the process and certain issues raised above, this section and the one that follows consist of a discussion of how the RAND Europe/HERG research team conducted the case selection and case study process in the arc research project. At the workshop 27-28 February we will discuss further how the selection of cases for Project Retrosight will take place.

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<sup>3</sup> Questions worth considering on this context include: What systems are currently used by the funders? Do we include HSR/AHP research as a separate category, and if so how should it be defined?

<sup>4</sup> Is this an important research question? If so what types of funding do the funders provide and how is each defined?

In generating the selection matrix for the arc project we identified three key characteristics of each grant: the type of funding, the area of research and the PI's level of success. Figure 2.2 provides an illustration of a sample selection matrix from a study of funding by the arc. The matrix has 16 cells concentrating on four main types of funding, two areas of research (clinical science and basic science) and two levels of success ("High" and "Mid"). A summary of how we classified grants in this instance is given in the following sections.

In the arc study we chose to classify according to funding mode as this is an obvious policy lever for arc in affecting the outcomes of the research that it funds. We chose to distinguish between two areas of research: basic and clinical, as we felt that they might be expected to produce different spectrums of feedback and, again, could be influenced by arc. Further, we wanted to examine researchers of differing levels of success to see whether the amount or pathways of translation for the types of researcher differed. The final reason for classification was to ensure that the case studies selected reflected the variety of grants that arc awards.

Project grants provide support of limited duration for a project designed to seek an answer to a single question or small group of related questions. Programme grants provide longer-term support and are awarded to established groups undertaking relevant research to answer an interrelated set of questions. Fellowships are awarded for a mixed duration to attract and retain talented clinical and non-clinical scientists in relevant research. In the arc study we used qualifications listed in the grants' database to classify PIs as basic scientists, clinical scientists or AHPs.

	<b>Basic science</b>	<b>Clinical science</b>
Project grants	High success	High success
	Mid-success	Mid-success
Programme grants	High success	High success
	Mid-success	Mid-success
Fellowships	High success	High success
	Mid-success	Mid-success
Institute funding	High success	High success
	Mid-success	Mid-success

Figure 2.2: A sample selection matrix for the arc study

During our key informant interviews it became clear that there were problems with the original selection matrix:

- the area of research carried out by AHPs, which was taking up an increasing proportion of arc research funding, was not similar enough to clinical science research to be considered within that category;
- in the case of work by AHPs, there were some funding types where no grants had been awarded;
- the two institutes that arc funded carried out research of very different types, with the Kennedy Institute concentrating on biochemical and cell biological research and the arc ERU specialising in epidemiology.

These developments meant that our selection matrix evolved into the one shown in Figure 2.3. The selection at this point was guided by three criteria:

1. trying to have at least four case studies in every group to compare – for example: four project grants to compare against four programme grants; or four “Mid” impact grants to compare against four “High” impact grants. This is analogous to experimental replication;
2. balancing the number of case studies against the level of funding committed to different areas and the number of grants awarded in those areas – for example: in our time window, AHP grants was the smallest area of funding and many of the fellowships awarded provided less than £1,000; consequently we only carried out two case studies on AHP work, both of which looked at project grants;
3. trying to avoid case studies that looked at the same subject area where possible – in one case (“Mid” Impact Clinical Project and “Mid” Impact Basic Manchester) we failed to achieve this and there are two case studies looking at very similar areas of research.

		Basic science	Clinical science	Allied health professional science
Project grants		High	High	High
		Mid	Mid	Mid
Programme grants		High	High	
		Mid	Mid	
Fellowship grants		High	High	High
		Mid	Mid	Mid
Institute funding	Kennedy Institute	High	High	
		Mid	Mid	
	arc ERU	High	High	
		Mid	Mid	

Figure 2.3: Example of a case study selection matrix used in arc

### Populating the selection matrix

To generate shortlists for each cell of the selection matrix, we performed the following:

- exported a list of all grants awarded between 1990 and 1994 from the arc funding database;
- selected and classified grants by funding type;
- classified the grants by area of work, using the PI’s qualifications; and
- examined each PI’s publication record to classify grants by success.

The process of populating the matrix was more complex than we had expected, mainly due to the level of sophistication required in the assessment of success by bibliometric measures.

### Complete list of arc grants from 1990–1994

arc had almost complete computerised records for all grants and applications since 1990. This database contained information on the size of grant that had been awarded and paid out, names of co-applicants, the title of the grant, the PI’s address, the type of funding and the location of archive records of the grant. This database made generating a list of all grants awarded between 1990 and 1994 very easy. This generated a list of 632 grants.

### Selection and classification by funding type

The arc grants database contained information on the funding type of each grant, and we used this information to classify candidate grants by funding type. In the early 1990s there were 14 types of grant;<sup>5</sup> we chose to concentrate on the four most significant funding streams and to group all fellowships into one category (see Box 2.2 for explanations of our

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<sup>5</sup> The types of grants awarded between 1990 and 1994 were: academic post, building grant, clinical research fellowship, core support grant, educational project grant, equipment grant, junior research fellowship, non-clinical career development fellowship, PhD studentship, postgraduate bursary, programme grant, senior research fellowship, special purpose grant and travelling fellowships.

categorisations). We chose to concentrate on the types of grants that make up most of arc's current funding and to look at the types of funding which are most likely to be affected by policy changes. This generated a list of 556 grants held by 357 PIs.

#### Classification by area of work

We classified the grants into the three areas of work: basic science, clinical science and AHPs, on the basis of the PI's qualifications between 1990 and 2001. This classification was reviewed then by the arc Scientific Secretary. With 357 PIs to classify we needed a technique that could be applied rapidly and that was reasonably clear cut. We did not think it was practical to classify grants from their titles alone and unfortunately, the arc grants database did not contain the grant abstracts that would have allowed a more nuanced classification.

#### Classification by success

This was the most complex part of shortlist generation. In the arc study we looked at the bibliographic record of each individual, ranked them and looked at the top ten per cent. As we will not be using this method in Retrosight we will not go into further detail about this method here.

#### Selecting the individual grants

The final selection of case study grants from the shortlist was carried out by the Development Committee using their knowledge of the field, the individuals involved and the variety of arc funding. In the early stages of the project we asked the members of the Development Committee to score, on a scale of 1 to 5, the shortlisted case studies before the selection meetings; scoring would be done on the basis of how interesting and useful they thought each grant would be as a case study. These scores allowed us to produce a reduced shortlist of case study grants. This list contained the four or five grants that had been scored the highest, for each cell of the selection matrix. The Development Committee then selected the case study grants from this list. In the later stages of the project the Development Committee selected directly from the complete shortlists.

## CHAPTER 3 Conducting case studies

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### Data collection and methods

The previous chapter discusses the use of case studies for shedding light on the process of research translation. When using case studies it is appropriate to draw on multiple sources of evidence relevant to the same issue, adopting a process of triangulation. If these multiple sources or methods produce findings that point towards and reinforce the same conclusions then this increases confidence in the conclusion. To construct the narrative for case studies using the Payback Framework, three independent sources have tended to be used: document and literature review; semi-structured interviews with PIs and other key informants; and bibliometric analysis. In this section we describe the process of data collection, including how the data collection proceeded in the pilot case for Retrosight and is expected to proceed in other Retrosight case studies, and illustrate also with examples of data collection from the arc research.

### Case study pilots

We have found that, given the novel aspects of this research, it has been useful to conduct a pilot case study. In the arc study we undertook three case study pilots and reported these to the Development Committee before proceeding with the subsequent 13 case studies. In the arc study issues arose in the pilot that it was then possible to feed in to the research process for subsequent cases. For example, one of the main issues that emerged from the arc pilot studies were the importance of interviewing the PI early in the process, prior to extensive review of subject specific documentation. For Project Retrosight we conducted a pilot case study in the UK. This case study will be circulated to participating researchers in conjunction with this research pack.

While we do not think it is necessary for the participant countries to conduct additional pilots, staggering the start of the case studies may be useful. We recommend separating them in to two tranches that kick off in succession rather than simultaneously.

### Approaching Principal Investigators

After selecting candidates for the case study, PIs are then approached by email and telephone.<sup>6</sup> We have found that all the PIs approached in arc, as well as the pilot case

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<sup>6</sup> See Annex C for a sample approach wording for emails, calls, etc.

study PI for Retrosight, consented to their grants being examined for the purposes of the research.

### Consent

It is important to obtain the PIs' written consent to participation in the research. This consent to participation entails agreement to the terms of participation set out in the consent form in Annex E. PIs should understand that although names can be removed, genuine anonymity is impossible, as informed observers are likely to be able to identify the researcher on the basis of the content discussed. PIs should also understand the nature and extent of the validation process in which they will participate in order to avoid misunderstanding later in the case study. This should be made clear either in the approach or at the outset of the interview.

### Document and literature review

A range of material should be reviewed including, for example, original grant applications; referees' reports; subsequent correspondence between the funding body and the grant holder; and the review of interim and end of grant reports where possible. In addition, case study analysts will read the peer-reviewed papers and reports that were considered by the PI to have arisen from the grant and other background literature. We found an additional way to get at documentation in the Retrosight pilot case by requesting information from the PI's base institution.

Other means of finding relevant documents include detailing a list of papers thought to be attributable to a particular grant such as end of grant reports and searching the Web of Science under their name.

### Semi-structured key informant interviews

Researchers conduct a range of interviews, including one with the PI, other named and unnamed staff on awards, collaborators and other stakeholders, including peers and users of the research. The interviews are based around the payback framework and explore the origins of the research, primary outputs and any translation of research findings into product development, policy and practice.<sup>7</sup> Most interviews are conducted face-to-face, with a few by telephone. Each interview for the Retrosight pilot case study lasted between 60 and 150 minutes. In addition, interviews are often followed up with email correspondence and telephone enquiries and clarifications. Interviews are recorded and these recordings are preserved for later reference.

### Grant history and diagram

This step was introduced in the Retrosight pilot to set out key influences on the award of the grant. Events thought to have influenced the genesis of the research were noted. In this we were primarily interested in broader contextual inputs to the research. However, this history should include only events believed to have had a relatively direct impact or significance for the particular grant under investigation, rather than wider contextual factors that would have influenced the research environment but not necessarily had a significant direct impact on a given project/grant. The data for this history was collected

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<sup>7</sup> See Annex D for interview protocols for PI and other KIIs

through key informant interviews. The aim is to then depict these influences and impacts diagrammatically as in Figure 3.1 below.

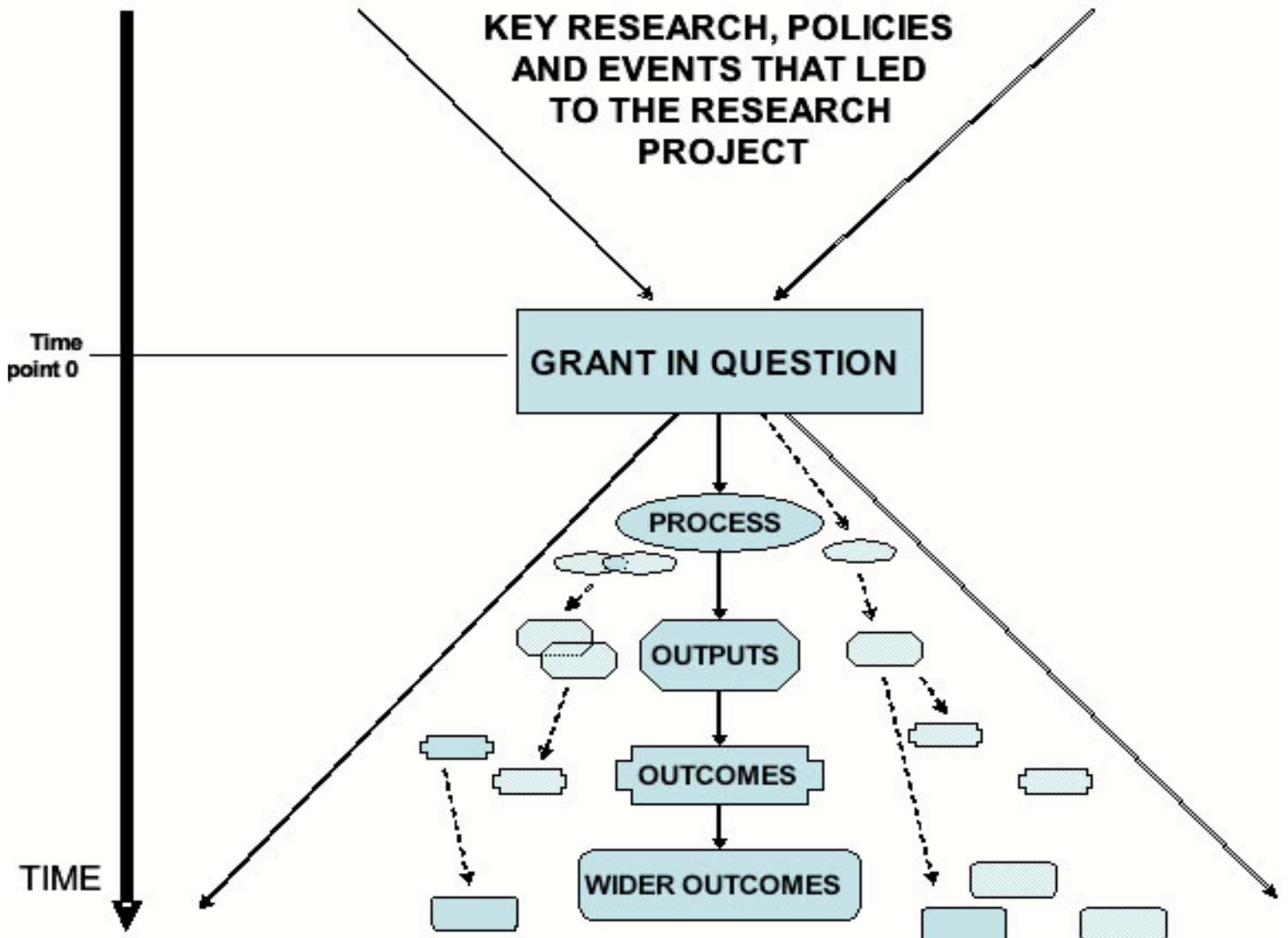


Figure 3.1 Diagram of grant history or genesis

**Bibliometric indicators**

For case studies the central project team will undertake a bibliometric analysis of the researchers selected for the cases. We will discuss this bibliometric analysis at the Retrosight workshop in Santa Monica 27-28 February.

**Reporting of case studies**

Case studies should be written up as a 10-15 page narrative structured by the Payback model. They should also contain a one page summary of the key points; a one page summary or table of outputs categorised as in the Payback model; a list of papers that came out of the grant; the history or pathway that led up to the research; and a signed consent and approval form for each of the case study participants (PIs, and in certain

circumstances other interviewees may also be included). The pilot case will be written up in the suggested format and circulated.

#### Clearance and validation

A draft copy of the case study report must be sent to the PI as a professional courtesy and for comment and approval. This clearance process validated our understanding of the case studies.

## CHAPTER 4    **Analysing case studies**

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This part of Retrosight will ‘collapse the complexity’ of the case studies by encompassing a cross-case or comparative analysis of the cases from the four countries.<sup>8</sup> This analysis will be built up from a series of insights including analysis of the qualitative observations of RAND Europe/HERG and the country researchers, as well as from the quantitative data or scores obtained from analysis by the international team of experts employed for this part of the research.

Using the evidence base generated by this multifaceted analysis we will carry out a detailed assessment of how basic research is translated into clinical practice, drawing out policy observations and recommendations that will be of use to biomedical research funders. In addition, we will then be in a position to provide a detailed catalogue of the paybacks from the research. The scale of the study should enable us to make a major contribution to understanding the way the results of basic or early clinical research eventually translate into application, providing invaluable information for policy makers within health R&D.

### Qualitative analysis

We will look to draw observations about the case studies at several levels, including comparisons of the apparent relative impact of specific personal or individual factors, observations about the funding process and about the evaluation of research, as well as methodological insights of value to the use of the Payback model. Box 4.1 below provides some examples of such observations from the arc research. These observations will then be collated and analysed to allow recurrent and especially significant themes emerging from the case studies to be identified. Each theme, the main issues and sub-issues will be discussed and validated with supporting and/or contradicting case study evidence.<sup>9</sup>

Observations about the process of arc-funded research and the development of that research, eg: “Where translation occurs, it occurs largely due to the personal networks of the PI.”

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<sup>8</sup> This is facilitated by the common structure of the case study reporting.

<sup>9</sup> See McFadzean (1998) for further details.

Observations about how arc monitors and evaluates its research, eg: “The arc does not have a comprehensive method of monitoring publication outputs that occur after the end of the grant.”

Observations about evaluating research in general, eg: “PIs with many grants tend to run their laboratories as ‘one pot’ of money, hence attributing outputs is difficult.”

Box 4.1: Examples of observations from arc research

## Annexes

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## Annex A: Discussion of Payback Categories

### Publications

The US National Science Board makes an annual assessment of national performance by publishing counts of scientific papers and patents in its “National Indicators” series (National Science Board 1996). Similarly, in the UK, the Research Assessment Exercise evaluation of university departments includes the submission of scientific papers as part of assessment procedures (Wooding and Grant 2003). More recently, the Office of Science and Technology (OST) has used bibliometric data for public sector agreement target metrics for the UK science base (Office for Science and Technology 2003). These types of bibliometric analyses have attracted their critics (Seglen 1997), not least because they have been used in isolation of other methodologies and have failed to use multiple indicators in the assessment of research (Martin 1996). At its most fundamental level, bibliometrics should be used to generate hypotheses rather than to provide conclusive evidence on a particular policy or intervention. In this study we have used a number of bibliometric indicators to inform our case studies (and the wider contextual analysis of the arthritis field), but these indicators are complemented by other information collected from the document and literature reviews and the key informant interviews.

In addition to counting the number of publications, their quality and impact can be assessed in various ways. Traditionally, the quality of knowledge production has been assessed by peer review, but various other methods can be applied. Often, papers that are accompanied by an editorial are seen as being of particular significance. For those studies that are included in a systematic review there are now formal quality assessment techniques (Grimshaw and Eccles 1998). Citation analysis can be applied to assess the impact that the specific article is having within the research community (Dawson and others 1998; Wellcome Trust 2001). Previous experience suggests that knowledge production will be particularly important for basic research, and certainly papers in basic research journals tend to be cited more frequently than those in clinical journals (Lewison and Dawson 1998).

A journal’s “impact factor” is based on the average number of times that an article in the journal is cited; this can provide a shorthand version of citation analysis by giving some indication of the importance of the journal in which an article appears. The use of impact factors in analysis of biomedical research has been criticised (Lewison and Dawson 1998), but provided that care is taken (Garfield 1996), it has been shown to be of some value (Lewison and Devey 1999; Wellcome Trust 2001).

Particularly when considering research that might be aimed at potential users outside the research community, it is often desirable to use a range of publication outlets, including those journals with the highest readership among the groups at whom the research is targeted. In some fields these may well be journals that do not have an impact factor but that are, nevertheless, significant as vehicles for dissemination of the knowledge produced (Hanney, Soper and others 2003; Jones and others 2004; Royal Netherlands Academy of Arts and Science 2002).

### Research targeting and capacity building

The better targeting of future research is frequently a key benefit from research, especially from research that is more basic and/or methodologically oriented. An indication of this comes from citation analysis. The targeting can be of both the research conducted by others and the original researcher(s). Where follow-on research (especially by members of the original research team) is clearly associated with the original research, it can be useful to obtain information on the source and amount of such funding. As is developed in the paragraph below, one of the key roles of a medical charity can be to fund research in its field that will help to open up questions or issues that will then attract further funding from general research funders such as the Medical Research Council (MRC) and the Wellcome Trust.

Research training can be provided both as a result of the employment of staff on research projects and programmes, and through explicit funding for research training and career development. One measure of research training which may appear crude but nevertheless has been used in previous studies, is the number and level of higher or research degrees resulting (either totally or in part) from the research funding (Mushkin 1979; Verhorn and others 1982). The career development of arthritis researchers goes much wider than specific training and is of considerable importance to arc, which aims to ensure that the pool of researchers in this field is as strong as possible. The reasoning is that this, in turn, should help to ensure that arthritis as a topic is able to gain an appropriate share of the research funding that is available from general medical research funders. Some of arc's funding schemes aim explicitly to provide career development, and for other researchers the receipt of a project grant from arc can be important in advancing their career in research.

### Informing policy and product development

Research can be used to inform policymaking in a wide range of circumstances. Policymaking here is interpreted very broadly to cover not only government national policies, but also:

- policies made by managers at many levels within a health service;
- policies agreed at the national or local level by groups of health care practitioners in the form of clinical or local guidelines; and
- policies developed by those responsible for training, education or inspection in various forms including training packages, curricula and audit and evaluative criteria (Hanney, Soper and others 2003).

Basic research is less likely than that from clinical researchers or allied health professionals (AHPs) to be used to inform policy.

On a similar level, although it involves very different processes, research can be used also to inform product development. Informing policies and product development are conceptually similar in that there generally has to be some subsequent adoption of the policy, or product, before the health and economic benefits can accrue.

### Health benefits

These benefits might be viewed as the “real” payback or outcomes from health research. Greater clinical effectiveness resulting from research-informed drugs or procedures will lead to increased health. Various measures of health gain do exist, but in most cases for arthritis the emphasis is likely to be on those that assess reduction in pain or disability, or increased mobility. While the benefits from arthritis research will not be generally measured in terms of life years gained, in principle they might be captured by using Quality Adjusted Life Years (QALYs). In countries such as the UK, this is seen as a more appropriate approach than using Disability Adjusted Life Years (DALYs) (Fox-Rushby 2002). There have been recent attempts to put a monetary valuation on the reduction in mortality and morbidity as a result of health research (Access Economics 2003; Murphy and Topel 2003); however, there have been criticisms of these approaches (Buxton and 2004).

This category of benefits can be thought of as going wider than health gain, and some aspects can be seen as benefits to the health sector more generally. Cost savings in the provision of health care may result from research-informed changes in the organisation of services, or in the particular therapies that are delivered. It might be necessary to consider various issues here. These include whether potential savings have been realised in practice – either as cash savings or the release of resources for other valuable uses (Hanney and others 2003). Furthermore, it would be important to check whether, for example, costs are not simply being transferred elsewhere. Improvements could arise also in the process of health care delivery; these could be measured by techniques such as patient satisfaction surveys.

### Broader economic benefits

A range of benefits can accrue to the national economy from the commercial exploitation of research. These can take the form of employment and profits resulting from the manufacture and sale of drugs and devices (Rosenberg 2002). The national economy could benefit also from exports and/or import substitution (Gadelha 2000; Hale and Towse 1995).

While there is a danger of double counting, it may be valuable to adopt a human capital approach and focus on the value of production that is gained from having a healthy workforce. This can be measured by examining the reduction in days off work. Typically, a human capital approach has been used, in which potential future earnings are calculated for people who, as a result of advances in medical research, can continue to contribute to national production; for example by reducing the days off work caused by low back pain (Drummond and others 1992; Mushkin 1979; Weisbrod 1983). However, those who use it share concerns that such an approach could have equity implications in assessing the benefits, in that it would seem to favour research that is relevant for those of working age. This concern might be relevant here in that many who suffer most from arthritis are retired. An additional concern is the value of the production lost from days off work may be overestimated if it is measured in terms of relevant wage-rates (Koopmanschap and others 1995).



## Annex B: Draft Protocol for Case Studies

1. Eight case studies will be conducted in each of the participating countries. They will be selected by the selection criteria detailed above.
2. Each case study will have three main sources of data.
3. Questionnaires [to be determined dependent on criteria for selection finalised in Workshop discussions]
4. Data collected in the case study:
  - Analysis of project files
  - Impact factor and citation data for publications
  - Review of abstracts or publications attributable to the grant for the majority of interviews
  - if possible, analysis of any documents referred to by the interviewee as demonstrating the impact of the project, including checking for examples of other evidence that might have influenced the relevant decisions;
5. Write-up of each case study on 10-15 pages using the stages of the payback framework as the organising framework, but with space for the points about possible additional areas of impact not captured by other methods.
6. Send draft of each case study to PI for comment

## Annex C Sample approach letter/email for PIs and other interviewees

For PIs:

Dear [potential interviewee name],

As part of a research team at RAND Europe, I am undertaking an English Department of Health supported project called Retrosight looking at the impact of cardiovascular disease (CVD) research over the last 20 years. RAND Europe ([www.rand.org/randeuropa](http://www.rand.org/randeuropa)) is a non-profit independent research organization which aims to produce high quality research and analysis for public policy.

Retrosight is a multi-national study to investigate how biomedical research influences health care. The study will look at research in cardiovascular disease over the past 10-20 years, and explore how research discoveries translated from the bench to the bedside. The study will comprise at least 32 case studies in four countries. Each case study will focus on a research group active in the early 90s and will explore the background to their work and how their ideas were built on and developed up to the present day. The study aims to increase our understanding of the research and translation process; to provide suggestions for improving the effectiveness and efficiency of scientific research; and to contribute to the accountability of research funders.

We are carrying out a case study looking at [case study researcher's name] research in [CVD study area] at [institute/university/hospital name]. During my meeting with [case study researcher's name], he mentioned that you would be an interesting person for us to speak to about the work he has been involved in since the early 1990s. The burden on you would be small, and likely to entail a telephone interview of around an hour and, potentially, an additional email to clarify points after the interview.

I have attached some additional information about project Retrosight and will endeavour to contact you in the next week. However, if you have additional questions, please do not hesitate to contact me. I very much hope that you are able to help us and I look forward to speaking with you.

Kind regards,

[your name here]



Retrosight Project  
Information...

**For other interviewees:**

Dear [researcher name],

I am undertaking a Department of Health supported project called Retrosight looking at the impact of Cardiovascular disease (CVD) research over the last 20 years. I work for a non-profit independent research organization called RAND Europe ([www.rand.org/randeurope](http://www.rand.org/randeurope)) which aims to produce high quality research and analysis for public policy.

Retrosight is a multi-national study to investigate how biomedical research influences health care. The study will look at research in cardiovascular disease over the past 10-20 years, and explore how research discoveries translated from the bench to the bedside. The study will comprise at least 32 case studies in four countries. Each case study will focus on a research group active in the early 90s and will explore the background to their work and how their ideas were built on and developed up to the present day. The study aims to increase our understanding of the research and translation process; to provide suggestions for improving the effectiveness and efficiency of scientific research; and to contribute to the accountability of research funders.

We would be interested in whether you think your area of research could provide a good case study and in whether you would consider being a case study for our research. The burden on you would be small, and likely to entail an interview of around an hour, access (if you have them) to your archived grant applications and some additional time to clarify points after the interview.

I have attached some additional information about project Retrosight and will endeavour to contact you in the next week. However, if you have additional questions, please do not hesitate to call me. I very much hope that you are able to help us.

Best regards,

[your name here]



Retrosight Project  
Information...

## Annex D Protocol for case study interview with PI

### Introduction:

RAND Europe is investigating the pathways upon which CVD research is built. RAND Europe is a non-profit policy research organization, with an interest in research policy. In order to carry out this project we are building a series of case studies around research grants that were awarded in the early 1990s.

RAND Europe works in a number of policy areas. This work is being carried out within our Science and Technology program which has an emphasis on research policy. Our previous work in this area includes: Payback studies of research impact on Arthritis Research Council grants and ESRC grants; a study for the National Audit Office on how Government Departments commission research published as 'Getting the Evidence'; and a study to investigate the views of academics with respect to research assessment for the Robert's Review of Research Assessment.

We are looking at both how the findings produced by the grant were developed and translated; and also, how the support developed the careers of researchers.

*You will probably want to quickly talk them through the Payback model at this stage.*

*You should also emphasize that not all the questions will be relevant to their research project, and indeed we wouldn't expect them all to be.*

*You shouldn't stick to the protocol as written, it just provides guidance of the areas you should aim to cover. During your desk research you will have identified additional questions that you will want to ask and it's probably best to add these to the protocol.*

### STAGE 0: Opportunity Identification/Research needs Assessment

1. What was the original impetus for your project? Solely scientific curiosity? The need to fill certain gaps in knowledge? Targeting of a particular disease state? Your own clinical experience?
2. How far was your identification of the research topic influenced by:
  - a. Research you had done before? Funded by whom?
  - b. The research of others? If so how did you hear about this research?

3. How much interaction was involved in determining your choice of research topic? With funders? With peers internationally in a specific research community? With representatives of patient or practitioner groups? Did institutional conditions such as lab space, equipment, availability of researchers affect the research proposal?

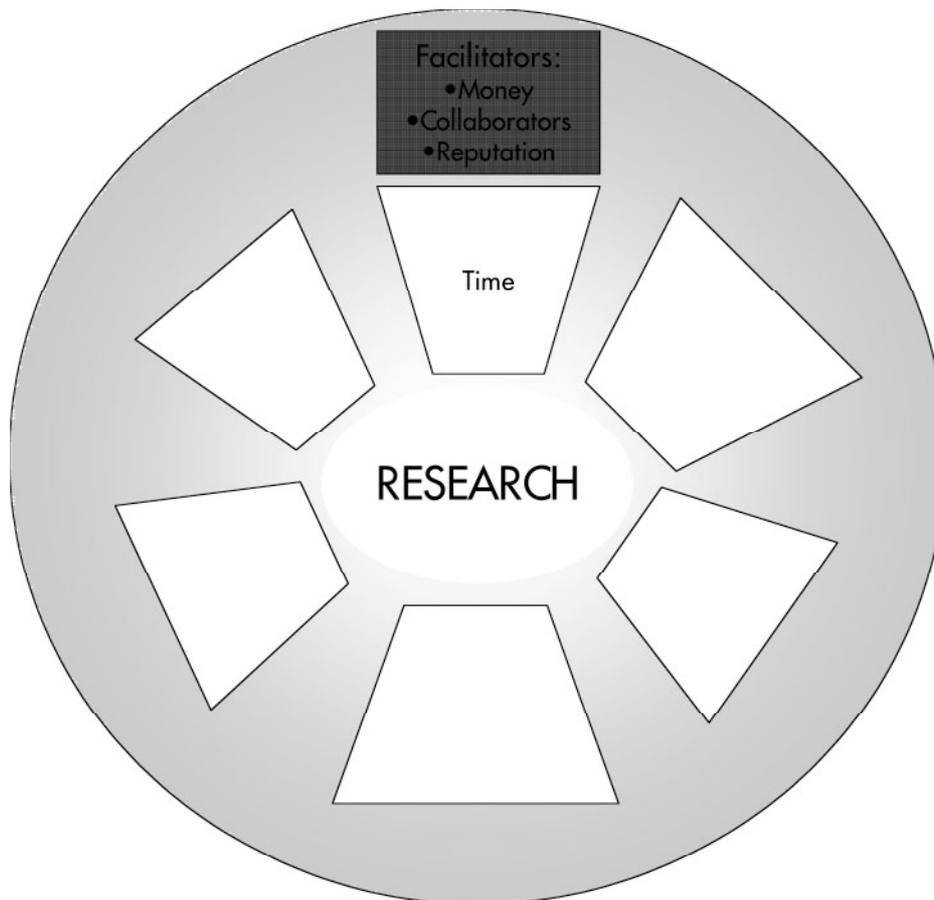
## INTERFACE A: Peer review/ Project Specification, Selection and Commissioning

1. Were any changes requested during the peer review/ project selection process?
2. Was there any negotiation involving potential users (users in any sense – maybe clinicians, maybe patients, maybe other scientists) during the project specification or commissioning processes?
3. Was there any involvement of practitioners, or even policy-makers, in the process of project selection?
4. Had your research not been funded by the organisation that did fund it, do you think any other body would have funded the research?

## STAGE 1: Inputs to Research

1. Check on cost of project. Were any other resources used on the project, for example where did the overhead costs come from? Was there soft or core funding?
2. What was the institutional setting (hospital, university, research institute) for the research?
3. Who were the main researchers? What was their level of research experience and seniority at that time and in particular had they previously worked in the research area?

4. What inputs of the following were important (provide a copy of the diagram and discuss around the topics):



## STAGE 2: Processes

5. Did the methods proposed prove to be appropriate? Were all of the avenues of research suggested in the proposal successful?
6. Was there any interaction with potential users of the research during the research processes?
7. What was your role as PI in the team and the research process? Facilitator? Research director?
8. What was the role of collaborators in the research process (both academic and industrial)?

## STAGE 3: Primary Outputs

*This section is reliant on the identification of a grant or piece of research from the 1989-1993 period.*

1. Identify any publications based on the grant that has been selected and from the subsequent stream of work following the grant.
2. Which publications do you think were most important from this project and why? *(Then reveal citation scores and compare results – based on preliminary Web of Science citation records or bibliometrics if available)*
3. Did this work have any impact on the agenda for your subsequent research?
4. Did it make any impact on the career of any of the research team eg contribute to research training in terms of research degrees or the gaining of additional skills? Enable them to establish themselves in the field? Assist in gaining further? Helping the lead researcher to build a team of researchers?
5. Are you aware of any other researchers who have built on this work or used the methods you developed? What is the role of collaborators in this?
6. Over what type of time-scale do you think your research influenced subsequent research.
7. Did the research spawn a new area of investigation or make a major impact on the approach used in subsequent research? If so would you go so far as to say it led to a paradigm shift in the understanding of a sub-field of arthritis or rheumatology?
8. If the research was clinical or related to AHP were any basic researchers also involved? If so did this influence their attitude to clinical or AHP research?
9. Were any health practitioners involved in assisting with the research, and if so did it have any impact on their attitude towards implementing research findings in general?
10. Did the project play any part in making the existing stock of international knowledge more applicable/acceptable in the UK? Did the project allow work from another field to be applied to arthritis and rheumatology or vice versa?
11. Has the research been included in any formal reviews? *In clinical science this would be a question about systematic reviews, in basic science it is a more general question.*
12. Have you had any impact outside the field of research you are working in?

## INTERFACE B: Dissemination

1. Apart from publications, what attempt did you make to disseminate the findings to academic audiences? More widely? Did you work with funders or stakeholders to do this?

2. Did you use specially designed dissemination approaches to particular audiences, for example policy briefs for policymakers? What were the most effective mechanisms for this?
3. What was the role of your networks in dissemination?
4. Did you receive support from funders/employers for dissemination? What form did this take?

#### STAGE 4: Secondary Outputs

1. Has the research been cited directly in any clinical guideline, audit criteria or similar document from a professional body or public policymaking body at national or local level?
2. Do you know how far the research directly influenced the formulation of any policy, or the realisation that a policy was needed?
3. Has any of the subsequent research by yourself or others that built on the project been cited in any clinical guideline, audit criteria or similar document from a professional body or public policymaking body at national or local level? Do you think this might happen in future?
4. Did the research from your project lead to any patent/licences, was it taken up by industry/has it contributed to any commercial products?
5. If the research has made some impact, what are the key reasons for this? If it has failed to have an impact what are the reasons for this? What **barriers** were there to the research having an impact/being translated? What factors **facilitated** the research having an impact/being translated?
6. Has your research had an impact on teaching for clinicians?
7. Has any advisory role to government, hospitals, industry led to an impact from your research? How did this come about?

#### Mapping exercise

8. Use a large sheet of paper (flip chart sheet) to map with the PI, the research. Both forwards from the grant under discussion and backwards to understand key inputs to the grant (people, money, expertise – see inputs section). Figure 2 shows an example of what this might look like.

## STAGE 5: Applications

1. Have the findings from the research influenced practitioners directly through them reading the articles or hearing a presentation about the research? Has it made any impact on practice through clinical guidelines or policies based either specifically on the research or on other research that built on your research? Has any impact been local, regional, national or international?
2. If the research has been taken up by industry, do you know what level of sales has been achieved by any product to which it contributed?
3. Do you expect any greater take-up of the findings in the future? Where?
4. Has there been an impact on practice through your own clinical work (if you have any)? What has been the knock on effect of that on other clinicians?

## STAGE 6: Public Engagement

1. Depending on answers to previous questions about involvement of the public in shaping the research agenda, ask how far there has been any interaction with patients, patient groups or the wider public about the findings and their implication. Has this led to any improvement in the way patients manage their own care or interact with therapy? Or had any impact on public attitudes to medical research?
2. Did engagement with the public/patient groups lead to changes in the researchers' perceptions of these groups?
3. Has there been a change in attitudes in the research community to involvement of the public since the time when this research was conducted?

## STAGE 7: Final Outcomes

1. If the research has made impact on policy or practice, or on the behaviour of the public, is there any way of assessing the benefits in terms of: patient health gain? Qualitative improvements in the way the service is delivered that increase patient and/or practitioner satisfaction? Cost savings?
2. If it is possible to assess the potential benefit for one patient, approximately how many patients might be able to benefit from the improved therapy or organisation of the service?

3. If the improved therapy based on the research has resulted in a health gain, will this also result in fewer days lost from work/ decreased benefits payments/ decreased visits to secondary healthcare?
4. If the research has resulted in commercial development is anything known about the amount of employment generated, the level of import substitution, or the revenue generated for the company by the product?

### Other general questions

1. Who else should we speak to about your research?
2. Are there other questions we should have asked or things that you want to talk about?
3. Are you happy for us to contact you to follow up on details arising from the case study research?

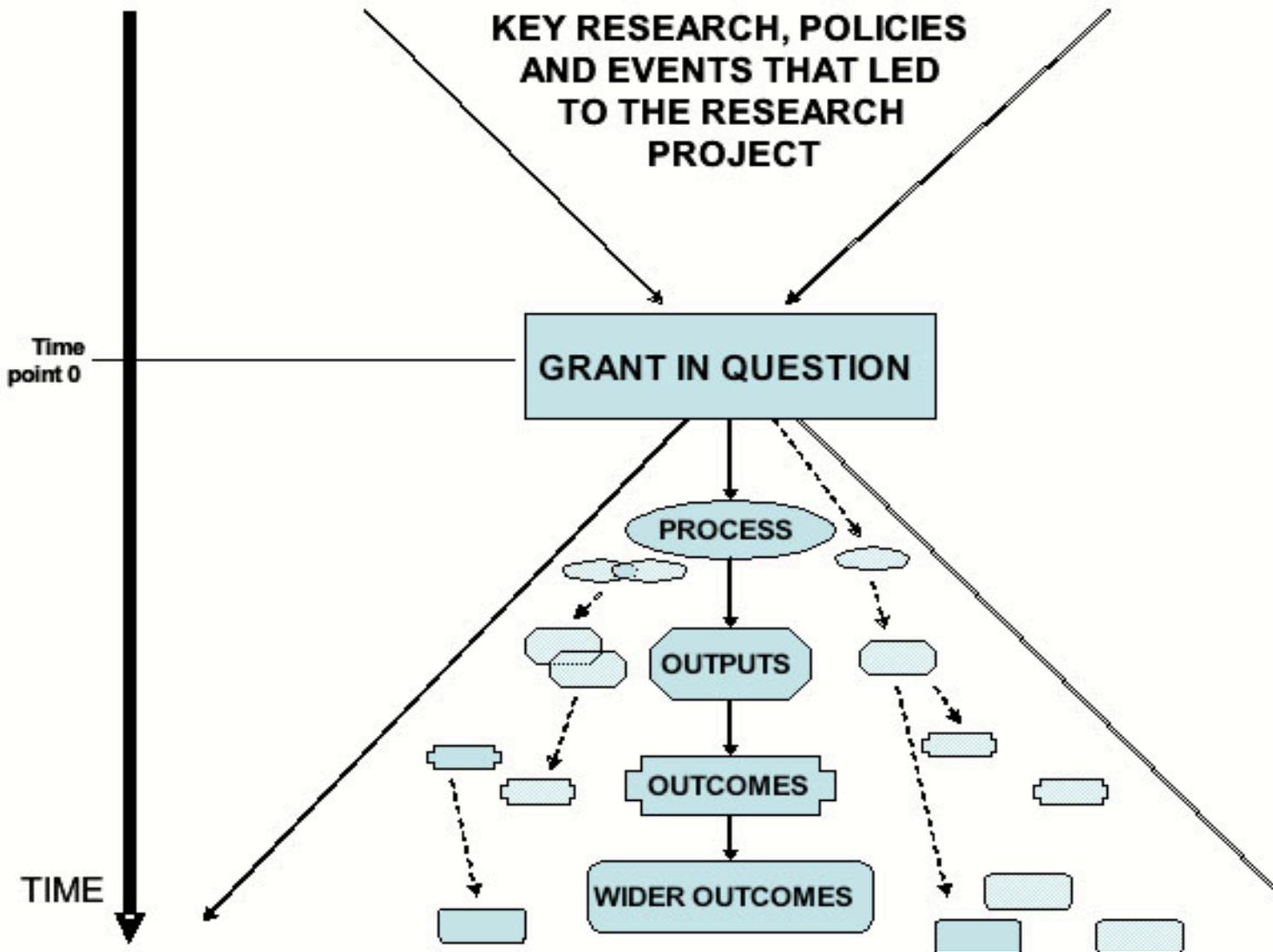


Figure 2. Example of mapping exercise. Dotted arrows represent potential links between key processes, outputs, outcomes and wider outcomes.

## Annex E protocol for non-PI interviews

### Introduction:

RAND Europe is investigating the pathways upon which CVD research is built. RAND Europe is a non-profit policy research organization, with an interest in research policy. In order to carry out this project for ARC we are building a series of case studies around research grants that were awarded in the early 1990s.

RAND Europe works in a number of policy areas. This work is being carried out within our Science and Technology program which has an emphasis on research policy. Our previous work in this area includes: Payback studies of research impact on Arthritis Research Council grants and ESRC grants; a study for the National Audit Office on how Government Departments commission research published as 'Getting the Evidence'; and a study to investigate the views of academics with respect to research assessment for the Robert's Review of Research Assessment.

We are looking at both how the findings produced by the grant were developed and translated; and also, how the support developed the careers of researchers.

You will probably want to quickly talk them through the Payback model at this stage.

You should also emphasize that not all the questions will be relevant to their research project, and indeed we wouldn't expect them all to be.

You shouldn't stick to the protocol as written, it just provides guidance of the areas you should aim to cover. During your interview with the PI/Lead researcher you will have identified additional questions that you will want to ask and it's probably best to add these to the protocol prior to the interview.

### General questions

1. What is your current position? What was your position during the lifetime of the grant?

2. How did you find out about the researcher? The research project in particular?

## STAGE 0: Opportunity Identification/Research needs Assessment

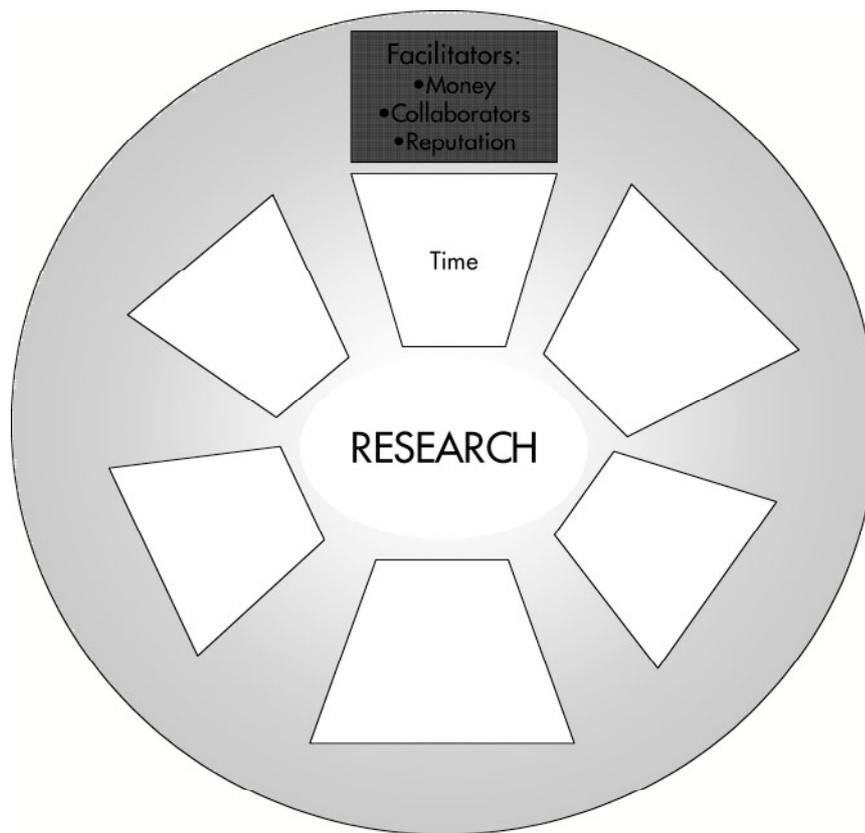
4. Did the project fill certain gaps in knowledge? Was there an urgent need for it (either scientifically or clinically)?
5. Did you have any input into the identification of the research topic/ funding body/ research team identification?
6. Do you know of other research at the time that suggested this project should be performed (either your own research or others)? What was going on in research in this area at the time? Was this a novel project?
7. [For co-researchers] How much interaction was involved in determining your choice of research topic? With funders? With peers internationally in a specific research community? With representatives of patient or practitioner groups? Did institutional conditions such as lab space, equipment, availability of researchers affect the research proposal?

## INTERFACE A: Peer review/ Project Specification, Selection and Commissioning

9. Were you involved in any negotiation during the project specification or commissioning processes?
10. Had the research not been funded by the organisation that did fund it, do you think any other body would have funded the research?

## STAGE 1: Inputs to Research

5. What inputs of the following were important in helping the project be a success? (See diagram):



## STAGE 2: Processes

1. From what you know, from what you know, were the methods used for the project suitable for the study? Were they groundbreaking/ building on previous research?
2. Was there any interaction with potential users of the research during the research processes?
3. If you were a collaborator in the research process, what was your role? (both academic and industrial)?

## STAGE 3: Primary Outputs

13. What specific outputs of the research/researcher do you know? What is your view on their work in general? On this project/subject area?

14. Which publications do you think were most important from this project and why?
15. Did this work have any impact on your own research/ the research field as you know it?
16. [For co-researchers] Did it make any impact on the career of any of the research team eg contribute to research training in terms of research degrees or the gaining of additional skills? Enable them to establish themselves in the field? Assist in gaining further? Helping the lead researcher to build a team of researchers?
17. Are you aware of any other researchers who have built on this work or used the methods?
18. Over what type of time-scale do you think this research influenced subsequent research?
19. Did the research spawn a new area of investigation or make a major impact on the approach used in subsequent research? If so would you go so far as to say it led to a paradigm shift in the understanding of a sub-field of CVD research?
20. What was the relationship between the clinical and basic aspects of the research? If the research was clinical or related to AHP were any basic researchers also involved? If so did this influence their attitude to clinical or AHP research?
21. Do you know of the research being taken on board and used in practice? What facilitated this?
22. Has the research been included in any formal reviews that you know of? *In clinical science this would be a question about systematic reviews, in basic science it is a more general question.*
23. Has the research had any impact outside the immediate field of research? Did the project play any part in making the existing stock of international knowledge more applicable/acceptable in the UK?

## INTERFACE B: Dissemination

5. Apart from publications, what other dissemination methods do you know of from this project? (Could be seminars, books, teaching, practice clinics, talks, presentations, etc...)? Where was this other dissemination (funders/ stakeholders conferences etc.)?
6. Was any particular method of dissemination useful for you? Useful for specific types of information?
7. What was the role of personal networks in this dissemination in your opinion?

#### STAGE 4: Secondary Outputs

9. Has the research been cited directly in any clinical guideline, audit criteria or similar document from a professional body or public policymaking body at national or local level that you know of?
10. Do you know how far the research directly influenced the formulation of any policy, or the realisation that a policy was needed?
11. Has any of the subsequent research by the researcher, or others that built on the project, been cited in any clinical guideline, audit criteria or similar document from a professional body or public policymaking body at national or local level? Do you think this might happen in future?
12. Do you know of any patent/licences or industry take up/contribution to any commercial products that arose from the research?
13. If the research has made some impact, what are the key reasons for this? If it has failed to have an impact what are the reasons for this? What **barriers** were there to the research having an impact/being translated? What factors **facilitated** the research having an impact/being translated?
14. Has the research project had an impact on teaching for clinicians?
15. What other routes do you know of that could lead to an impact from the research (e.g. any advisory role to government, hospitals, industry)? How would/did this come about?

## STAGE 5: Applications

5. Have the findings from the research influenced practitioners directly through them reading the articles or hearing a presentation about the research? Has it made any impact on practice through clinical guidelines or policies based either specifically on the research or on other research that built on your research? Has any impact been local, regional, national or international?
6. If the research has been taken up by industry, do you know what level of sales has been achieved by any product to which it contributed?
7. Do you expect any greater take-up of the findings in the future? Where?
8. Has there been an impact on practice through the clinical work of the researcher involved that you know of? What has been the knock on effect of the research on other clinicians?

## STAGE 6: Public Engagement

4. Do you know how far there has been any interaction with patients, patient groups or the wider public about the findings and their implications. Has this led to any improvement in the way patients manage their own care or interact with therapy? Or had any impact on public attitudes to medical research?
5. Has there been a change in attitudes in the research community to involvement of the public since the time when this research was conducted?

## STAGE 7: Final Outcomes

5. If the research has made impact on policy or practice, or on the behaviour of the public, is there any way of assessing the benefits in terms of: patient health gain? Qualitative improvements in the way the service is delivered that increase patient and/or practitioner satisfaction? Cost savings?
6. If it is possible to assess the potential benefit for one patient, approximately how many patients might be able to benefit from the improved therapy or organisation of the service?

7. If the improved therapy based on the research has resulted in a health gain, will this also result in fewer days lost from work/ decreased benefits payments/ decreased visits to secondary healthcare?
8. If the research has resulted in commercial development is anything known about the amount of employment generated, the level of import substitution, or the revenue generated for the company by the product?

### Other general questions

4. Do you think that there is anyone else we should speak to about the research?
5. Are there other questions we should have asked or things that you want to talk about?
6. Are you happy for us to contact you to follow up on details arising from the case study research?

## Annex E

### Participant Consent background and issues

In the UK there are two ethical regulation structures: one for the health system and one specific to individual institutions. There are also at least two different areas that may dictate the need for the research for Retrosight to go to ethics committees. The first is that procedurally, it may be required by participating institutions. Second, legally or ethically the research may be contentious because of the context or content of the research. We believe that, at least according to our understanding of current regulations in the UK, it is not legally/ethically necessary for Retrosight research to go to health research ethics committees because we will not be seeking any data from patients or about individual patients. However, it is still possible that procedurally individual institutions may require ethics approval for the research (as may be the case for HERG at Brunel, for example). Further, whether or not the research conducted for Retrosight requires approval by a health research ethics committee may differ by country.

In the UK the RE/HERG team will be responsible for obtaining any necessary ethics approval for the overall Retrosight project, and the UK arm, from Brunel University's ethics committee. Please note that each partner country will be responsible for obtaining ethics approval in the appropriate way for the case studies conducted in their country.

Despite differences in national processes for obtaining ethics approval, it would be useful for the overall Retrosight project if each country attempted to use as common an approach as possible to some of the key aspects of obtaining participant consent. Although PIs' names can be removed if necessary, genuine anonymity is impossible, as it will almost

certainly be possible for an informed reader to glean the identity of the interviewee on the basis of content. This will need to be made clear both to relevant ethics committees and on the participant consent form. Then there is the question of using information from interviews with the PI, and any other interviewees.

In our previous studies the PI's agreement has always been obtained for the case study to take place before any work on it is undertaken. This agreement should include signed written consent to participation (this could possibly be an email), including the terms of participation with respect to commenting or signing off on the report of their case study.<sup>10</sup>

In terms of publication/veto, our suggested protocol for PIs and other interviewees is that at interview they should clearly specify what (if anything) in the conversation should be unattributable. Upon completion of the case study report, we suggest sending the draft report to the PI (and relevant parts to other interviewees) to read and comment within a set timescale (suggested three weeks, then a further two week reminder if necessary)). The default, unless the researcher hears back from the PI (and other interviewees if applicable) within the agreed timescale, is that the case study will then be considered as approved.

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<sup>10</sup> As set out in our article on the ARC methods this is more than just a matter of professional courtesy but an important part of the validation process: <http://www.health-policy-systems.com/content/pdf/1478-4505-2-4.pdf>

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