

# **Translational and Clinical Medicine Study**

Report to Scottish Enterprise

September, 2010



# SQW

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<b>Contact:</b>	Stewart Brown	Tel:	0131 225 4007	email:	<a href="mailto:sbrown@sqw.co.uk">sbrown@sqw.co.uk</a>
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<b>Approved by:</b>	Dr Stewart Brown	Date:	27.9.10
	Associate Director		

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# Executive summary

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1. This is a summary of a report from SQW on a study of translational and clinical medicine (TCM<sup>1</sup>) in Scotland conducted for Scottish Enterprise (SE) during January to April, 2010.
2. The prime objectives are:
  - to assess progress to date and areas of likely future impact of current TCM-related interventions supported by SE
  - to identify how Scotland's current competitive position in TCM can be transformed into economic growth - the potential routes to the economic 'prize' and how Scotland is positioned to realise this
    - and in this context, to assess whether current interventions are fit-for-purpose
  - to help SE understand the role it should play within the wider TCM landscape
  - to design an appropriate monitoring and evaluation framework for SE's TCM activities.
3. Five current TCM-related interventions are within the scope of the brief for this study:
  - Translational Medicine Research Collaboration (TMRC)
  - NHS Research Scotland – specifically the Permissions Coordinating Centre (NRS Permissions CC) which is a component of the wider NRS initiative
  - Scottish Academic Health Sciences Collaboration (SAHSC).
  - Scottish Health Innovations Limited (SHIL)
  - Edinburgh Bioquarter.

## Methods

4. The study used desk-based and primary research methods. Secondary sources of evidence include:
  - documents provided by the client containing descriptions of the existing interventions – supplemented by web-based public domain descriptions
  - documents provided on the current Life Sciences Strategy and on prior research
  - web-derived information on TCM activities in comparator locations.
5. Primary research was undertaken using either telephone interviews or face-to-face consultations with 19 individuals from different parts of the TCM 'landscape' in Scotland:

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<sup>1</sup> The Cooksey Report ([http://webarchive.nationalarchives.gov.uk/+/http://www.hm-treasury.gov.uk/d/pbr06\\_cooksey\\_final\\_report\\_636.pdf](http://webarchive.nationalarchives.gov.uk/+/http://www.hm-treasury.gov.uk/d/pbr06_cooksey_final_report_636.pdf)) states that translational research describes the work needed to bring an invention from pre-clinical into human trials. However, as discussed in the main report the term 'translational' is used in various ways.

- NHS Scotland – individuals with senior corporate roles and with lead R&D roles
- Chief Scientist Office, Scottish Government Health Department
- senior academic posts in Scottish universities
- senior executive posts in Scotland-based companies with an interest in TCM
- staff in SE and Scottish Development International (SDI).

## Progress and future impact

6. On progress to date and likely future impact of current TCM-related interventions supported by SE, we conclude the following:

- substantial achievement has been made in enhancing collaboration within and between the academic sector and the NHS (e.g. TMRC, NRS and SAHSC)
- the collaboration that attracted Wyeth and formed the TMRC was a notable achievement
  - however, in all of the above, significant benefits for the indigenous TCM-related business-base are yet to be realised
- the NRS Permissions CC appears to have made good, early progress in achieving efficiencies in NHS procedures for approving multi-centre trials
  - added value for indigenous CROs over their competitors is yet not clear
  - there is some growth expected in trials opportunities in Scotland as a result of the NRS Permissions CC initiative
- although reporting individual commercialisation successes, the views obtained on the efficacy and impact of SHIL were mixed. We understand the business model for SHIL is under review and this is timely
- Bioquarter is a new initiative but has enjoyed early, if relatively small scale endorsement of its attractiveness following a recent announcement of an inward investor taking space on the site.

7. Other potential for economic growth exists in replicating the inward investment achieved by the TMRC through the work of the SAHSC on pan-Scotland translational research initiatives. However, this may be largely to the direct benefit of revenue for the research base and NHS rather than indigenous businesses. Other than CROs who have benefit from the procurement of services, the other benefits to the Scottish economy of TMRC and SAHSC will rely on the commercialisation of IP from translational research by new or existing Scottish firms (or other forms of knowledge exchange of business value). Here the challenges are the same as face SE in supporting the commercialisation of university IP more generally. A number of consultees pointed to opportunities from the commercialisation of research into biomarkers.

8. Bioquarter offers an additional attractor for inward investment to complement the factors associated with research excellence and the Scottish healthcare system that proved attractive to Wyeth when joining the TMRC. Both here and elsewhere in Scotland, high quality

employment space and a critical mass of translational research excellence, with its accompanying complement of research-trained staff and post-graduate students, all contribute to Scotland's attractiveness as a location for Life Science companies.

9. It is relatively straightforward to 'fit' activity in support of TCM to government policy and SE strategy: it is relatively straightforward to confirm the market failure rationale for support. A key feature of many of the existing interventions has been their focus on addressing what were presumably seen as co-ordination failures to be overcome (or opportunities from enhanced co-ordination to be exploited). The TMRC, NRS Permissions CC, SAHSC and even the coming together of various Health Boards to form SHIL are all associated to a large degree with issues of co-ordination and strategic collaboration between individual (and in some cases diverse) organisations for the good of the Scottish economy. Bioquarter is also a collaborative venture.
10. The key uncertainty is the time to realising optimum impact of the existing interventions, notably the TMRC, SAHSC and Bioquarter. The efforts to attract additional trials to Scotland can, when successful, bring short term economic benefit, albeit possibly on a limited scale. The implementation of plans for Bioquarter has already attracted inward investment (the proposed location to Bioquarter of TPP Global Development) and the initiatives involving the academic research base aim to attract further investment in TCM capability and activity to the Scottish university sector. These and other attractors of academic research and commercial investment will operate over the medium to long term (e.g. the economic impact appraisal for Bioquarter suggests it will be c. 25 years before the vision is delivered in full). Indigenous business growth as a consequence of the commercialisation of IP is an ongoing process and one that inherently has an uncertain rate of 'build'. SE's own business intelligence available from its account management and high growth business start-up support functions may offer one route to obtaining empirical evidence on the likely economic 'build rate' at least over the next c. 5 years.
11. Whilst there was a broad consensus on the quality of CRO capability in Scotland, the potential for significant future growth of business for them in Scotland was less clear cut. Taking a wider perspective, the changes in the business models of large pharma companies and their increasing interest in business opportunities offered by emerging markets (i.e. outside of Europe and North America) may bring growth opportunities for those CROs with an international reach.
12. The business strategies of big pharma towards predictive medicine are also likely to be important in terms of determining growth opportunities for diagnostics companies. Some consultees suggest that pharma companies may develop in-house diagnostics development capability whilst some may rely more on acquisition of smaller, specialist firms. Outsourcing/strategic relationships may also develop.
13. The vision for the TMRC is 'to create a world class centre of excellence in biomarker discovery and utility'. Although some informants suggest that strengths in biomarker development in Scotland will continue to act as a magnet to attract investment, another argued that the healthcare re-imbursement model in the USA is likely to make opportunities there much more attractive to investors. Notwithstanding this caveat, there is general support for the proposition that biomarker development will prove to be a key route to business and economic growth for Scotland.
14. We also encountered quite divergent views on the positioning of diagnostics companies within the 'system' in Scotland, from: 'diagnostics companies are more stand-alone (than CROs) in

terms of their position in TCM in Scotland’ to ‘there are strong links between TCM and diagnostics – with growth in TCM there will be a parallel growth in diagnostics’.

## Competitive positioning transformed to economic growth

15. There is a fairly widespread endorsement of the view that Scotland is well positioned internationally with respect to the competitive position of its TCM-related assets – its research and clinical excellence; the characteristics of its healthcare system and its cadre of CROs. The point is also made that the TMRC is a validation of Scotland’s attractiveness to big pharma.
16. Two points need to be made however: (i) there is a widespread recognition that Scotland’s position with respect to commercialisation achievements lags behind its research and clinical excellence; and (ii) there is a strong sense that TMRC may not be meeting early economic development expectations.
17. Commercialisation linked to replicating the inward investment of the type associated with TMRC is a key path to transforming competitive position in research and clinical medicine into economic growth. Both these issues therefore require close attention by SE. Growth in business for CROs (including for science added value pre-clinical and other early stage trials) may be a spill-over benefit from this but it is unlikely to be a driver of growth.
18. In this context, the ‘jury is still out’ over whether the SAHSC can transform Scotland’s competitive assets in research and clinical excellence into economic growth. On commercialisation specifically, it is likely to be the ‘standard’ products in SE’s toolkit to support commercialisation and innovation that may be more useful than the current set of TCM-related interventions by themselves.
19. Based on the review of TCM in other locations internationally, the following high level lessons emerge, many of which Scotland has already taken on board:
  - many areas promote and build on existing reputation and capabilities created over extended periods of time, including:
    - the history and ‘pedigree’ of people and institutions, commonly classed as world-leading in their field
    - presence of renowned anchor organisations within the area e.g. academic institutions, medical research-intensive hospitals and presence of multi-national corporations
  - there is a strong emphasis on good governance structures for collaborative initiatives
    - there is common use of cluster and/or Triple Helix<sup>2</sup> concepts and implementation frameworks
    - linked to this, there is close attention to networking and bottom-up approaches
  - exploiting market potential facilitated by:

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<sup>2</sup> The Triple Helix model is concerned with harnessing and leveraging the complementary expertise of academia, industry and government to facilitate new systems for innovation and novel collaborative processes.

- existing commercial strengths in the area - entrepreneurs, investors and multi-national company engagement
  - realising future impacts enabled through integrated or ‘systems’ appreciation of contributions from:
    - financial capital (invested in infrastructure and enterprises)
    - from public and private sector sources, and from seed funds through to major foreign direct investment
    - human capital (labour pool, skills and volunteers for clinical trials)
    - knowledge capital (research excellence and invention)
    - understanding and alignment of regional and national systems of innovation.
20. It is evident that other countries are facing similar challenges in increasing the successful translation of health research into health *and* economic benefits, albeit each country is tackling the challenges in different ways, with no overall ‘right answer’ which could be emulated in Scotland. What is also evident is that the ‘challenge’ has been attracting significant public investment in new facilities and collaborative ventures, including elsewhere in the UK.

## Enhancing the TCM-related business environment - role and next steps for SE

21. From all the suggestions made by consultees, we would advise that the following issues be given priority attention by SE:
- a re-assessment of how much value-adding collaboration is ongoing within all the current interventions that has an influence and beneficial impact *specifically* on indigenous businesses
  - the nature and feasibility of enhancing further the exchange of knowledge and people between the research-base and indigenous businesses e.g. through Knowledge Transfer Partnerships, internship programmes and other means attractive to individual businesses
  - on marketing of the TCM interventions, to re-assess the efficacy of marketing efforts towards pharma companies internationally (not least in our view due to the ongoing changes in the structure of this international industry, including closure of R&D facilities and outsourcing), towards investors (inward investors and risk capital investors) and towards indigenous companies.
22. From the evidence gained from the study more generally, we conclude that there is a need to articulate much more clearly towards the business-base in Scotland the relevance to them of the TCM initiatives that are already being supported and to monitor and evaluate the actual benefits to business in Scotland that are delivered over time. Notwithstanding the relative immaturity of some of the interventions, there is a sense of their dislocation from Scotland’s business base which may presently derive more benefit from access to SE’s ‘standard products’. We also sense that there remains work to be done to encourage industry leadership and action in the



implementation of business-relevant initiatives, working pro-actively and collaboratively, rather than SE ‘owning’ all the challenges.

23. Raised awareness within the relevant business-base in Scotland of the nature and potential business value of the current TCM-related interventions is a preparatory step towards encouraging greater industry leadership in implementing strategies to enhance the TCM-landscape in Scotland for business and economic development purposes.
24. In addition to the catalytic and facilitation roles SE should continue to play in supporting the development of the TCM-related business environment, a key role is to deploy effectively its ‘standard’ toolkit of support to ensure that translational research (including especially biomarker research where informants point to good growth opportunities) conducted now and in the future through initiatives such as TMRC and SAHSC is commercialised to the benefit of the Scottish business-base and economy. Growth in demand for and take-up of for example its investment, business start-up and business growth-related products for TCM-derived business opportunities will be an important indicator that upstream investment in the research-base is bearing other economic development benefits.
25. With uncertainty over the time to realising optimum impact of the existing interventions, it will be important for SE to maintain a good level of knowledge of what is in the ‘pipeline’ of commercial leads and prospects associated with translational activities. Effort should be directed towards ensuring a portfolio of outputs that will bring short, medium and longer term benefits
26. There also remains a key role for SDI in developing prospects for inward investment, a role that is crucial to the success of SAHSC and Bioquarter. Also, it is relevant to note the importance of exporting to many of the businesses consulted during this study.
27. Specifically in terms of CROs in Scotland, we would suggest that a key role for SE is to provide the kind of ongoing support delivered by its account managers and to ensure that the nature and relevance of the existing TCM-related interventions are communicated effectively to these CROs as well as to other relevant businesses in Scotland. Developing the ‘message’ on TCM for business ‘clients’ and gauging their response will provide SE with one ‘acid’ test of the business relevance of the current TCM-related initiatives it is supporting.
28. Finally, preparatory to future evaluation of the various TCM-related interventions, we advise that SE re-assesses the adequacy of its baseline evidence on business and economic performance in this area.



# 1: Introduction

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- 1.1 This is a report from SQW Consulting on a study of translational and clinical medicine (TCM) in Scotland conducted for Scottish Enterprise (SE) during January to April, 2010.

## Purpose and scope

- 1.2 The prime objectives are:
- to assess progress to date and areas of likely future impact of current TCM-related interventions supported by SE
  - to identify how Scotland's current competitive position in TCM can be transformed into economic growth - the potential routes to the economic 'prize' and how Scotland is positioned to realise this
    - and in this context, to assess whether current interventions are fit-for-purpose
  - to help SE understand the role it should play within the wider TCM landscape
  - to design an appropriate monitoring and evaluation framework for SE's TCM activities.
- 1.3 Five current TCM-related interventions are within the scope of the brief for this study:
- Translational Medicine Research Collaboration (TMRC)
  - NHS Research Scotland – specifically the Permissions Coordinating Centre (NRS Permissions CC) which is a component of the wider NRS initiative
  - Scottish Academic Health Sciences Collaboration (SAHSC).
  - Scottish Health Innovations Limited (SHIL)
  - Edinburgh Bioquarter.

## Methods

- 1.4 The study used desk-based and primary methods. Secondary sources of evidence include:
- documents provided by the client containing descriptions of the existing interventions – supplemented by web-based public domain descriptions
  - documents provided on the current Life Sciences Strategy and on prior research
  - web-derived information on TCM activities in comparator locations.
- 1.5 Primary research was undertaken using either telephone interviews or face-to-face consultations with 19 individuals from different parts of the TCM 'landscape' in Scotland:
- NHS Scotland – individuals with senior corporate roles and with lead R&D roles
  - Chief Scientist Office, Scottish Government Health Department

- senior academic posts in Scottish universities
  - senior executive posts in Scotland-based companies with an interest in TCM
  - staff in SE and Scottish Development International (SDI).
- 1.6 Consultees were selected with advice from the client (see Annex B). It is important to state that given the number of informants, no statistical robustness is claimed for the primary evidence presented in this report.
- 1.7 The Study Team engaged with SE staff in the course of two ‘steering’/reporting meetings.

### ***Style of reporting***

- 1.8 Due to its access to well-informed, senior people in the research-base, government and industry, the primary research has elicited a wealth of information, insights and suggestions for future action. However, overall the evidence is characterised by: (a) its subjective/qualitative nature – generally consultees were unable or unwilling to offer quantitative assessments of likely business or economic impact from TCM, even estimated ones; (2) its marked diversity and indeed in many cases a polarisation of view. The latter point in particular has influenced reporting style: whilst providing conclusions and recommendations based on analysis and interpretation, we have felt obliged in places to adopt a narrative style in order to represent contrasting views and avoid over-interpretation.

### **Structure of the report**

- 1.9 The remainder of the report is structured as follows:
- *Section 2:* describes the policy and strategic context, and draws on prior research into TCM in Scotland
    - we also discuss the use of the term ‘translational and clinical medicine’
  - *Section 3:* reviews the TCM interventions currently supported by SE, based both on desk research and the views of consultees
    - these reviews lead to an assessment of routes to potential economic impact
  - *Section 4:* reports the views of consultees on the likely business and economic development contributions from TCM in Scotland, both present and future potential
  - *Section 5:* examines Scotland’s competitive position (strengths and weaknesses)
    - it tests four strategic propositions drawn from SE’s own view on the positioning of TCM in Scotland
    - it also examines the role that SE might play in future
  - *Section 6:* extracts learning from a desk-based review of comparator locations
  - *Section 7:* develops a monitoring and evaluation framework to track and assess the contribution of TCM-related interventions to Scotland’s economy, short and long term
  - *Section 8:* is a summary of overall conclusions and recommendations.

- *Annex A:* contains tables with details of the monitoring and evaluation framework proposed for each of the current TCM-related interventions
- *Annex B:* lists consultees contributing to the primary research
- *Annex C:* contains profiles of comparator locations.

## 2: Context

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- 2.1 In this section the strategic context for the development of TCM in Scotland is described briefly. Prior research into TCM in Scotland is reviewed. All provide insights into capabilities/activities and envisaged routes to economic benefit which underpin later assessment of current interventions and the findings of primary research. Finally in this section, we discuss the question: ‘What is TCM?’

### Economic policy context

- 2.2 As indicated in its Business Plan for 2010/13<sup>3</sup>, SE operates within the policy context set by the Scottish Government’s Economic Strategy<sup>4</sup> (GES): the latter sets out the main drivers which will increase sustained economic growth across Scotland:

- increase productivity and competitiveness
- solidarity: reduce inequalities across all individuals
- cohesion: reduce the disparity between the regions of Scotland
- sustainability: enhance the environment and reduce emissions
- stimulate population growth
- stimulate economic participation.

- 2.3 SE specifies its own priorities within the context of the GES and of the Government’s more recent Economic Recovery Plan. In summary, these are:

- support internationalisation, by assisting companies to expand into new international markets with significant growth potential
- assist companies with opportunities to commercialise by improving links between businesses and Scotland’s research base, and to innovate to take advantage of opportunities in domestic and international markets
- improve access to finance for businesses
- encourage businesses to invest in management and leadership skills, and in their workforce
- position Scotland as a highly competitive location for inward investment
- work with Scotland’s Industry Advisory Groups to develop and deliver industry-led strategies, alongside other public sector partners.

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<sup>3</sup> See: <http://www.scottish-enterprise.com/about-us/se-whatwedo/~media/publications/About%20Us/business%20plans/businessplan20102013.ashx>

<sup>4</sup> See: <http://scotland.gov.uk/Resource/Doc/202993/0054092.pdf>

### *Points of significance for this study*

- 2.4 In the context of TCM, the driver of economic growth most directly relevant is ‘increase productivity and competitiveness’. However, although improvements to the efficiency of NHS procedures for permitting clinical trials in Scotland (through NRS Permissions CC) will bring some competitive advantages to Scotland, the optimum added value benefit to the economy from TCM in Scotland may only emerge over the longer term. These benefits can derive from commercial activities, but of course TCM is important in delivering enhanced health outcomes which can have spill-over benefits to the economy over time.
- 2.5 A number SE’s current priorities are especially relevant to TCM. As reported later:
- *on internationalisation* - many of the companies consulted point to the prime importance to their business of international markets. Access to IP of commercial value from indigenous TCM-related research activity can if commercialised open up international market opportunities for Scottish companies
  - *on commercialisation* – one route to economic development benefit is to see Intellectual Property (e.g. in the area of biomarkers) developed in Scotland’s research base: (a) exploited by new or existing indigenous companies; and/or (b) act as an attractor to inward investors who locate business units close to the academic research
  - *on access to finance* – building businesses of scale from the commercialisation of the above IP crucially depends on access to ‘smart’ risk finance. The successful incubation of high growth firms associated with interventions such as Bioquarter is likely to depend to a large extent on access to risk capital
  - *position Scotland as a location for inward investment* – this is a prime objective of Bioquarter. The track record of engagement with a major pharma company achieved by the TMRC is seen as an exemplar that may help attract other similar inward investments
  - *work with Industry Advisory Groups* – the Life Science area is one in which engagement with industry has already resulted in the development of industry-led strategies and, in the specific context of TCM, has seen a number of collaborative initiatives involving industry, universities and different parts of the public sector.
- 2.6 In short, the nature and focus of existing TCM interventions, the expressed requirements of businesses and the issues around realising future growth potential in this area ‘fit’ well with the current SE response to Government policy. The main uncertainty is the likely time to realisation of optimal economic impact: it is likely to be long term relative to the timescale of SE’s business planning.

### **Life Sciences context**

- 2.7 The capabilities and activities associated with TCM in Scotland form a component of the country’s Life Sciences sector, a sector identified as of key importance in the GES.
- 2.8 The current Life Sciences Strategy for Scotland (2020 Vision: Achieving Critical Mass) is a refresh of the 2005 strategy (of the same name). Overall strategic leadership is provided by the

Life Sciences Advisory Board (LiSAB)<sup>5</sup>. Formed in 2009, the Board builds on prior work of the Life Sciences Advisory Group. LiSAB is co-chaired by a Scottish Government minister and an industry representative, and has a membership drawn from different parts of the industry, the university and the public sectors.

2.9 The ‘vision’ set for 2020 places emphasis on the following issues:

- achievement of critical mass
- global orientation
- “fully connected” Life Sciences sector
- collaborative action
- exploitation of scientific strengths plus “financial services and innovative business models”.

*Points of significance for this study*

2.10 There is a notable emphasis in current TCM-related interventions on enhancing the ‘connectedness’ and collaboration in the Scottish academic research-base and the NHS in Scotland. These include collaborative working to attract clinical trials and collaborative research to Scotland and to reproduce the success in attracting a global pharma company to the TMRC. However, as will be reported later, the degree of engagement achieved to date by most of current TCM-related interventions with indigenous businesses seems from our sample rather limited.

2.11 Also, given the diversity of scale of TCM activities and capabilities in comparator locations, the meaning of “critical mass” for Scotland merits further consideration of baselines and desired future scale.

**Sector focus of Scottish Enterprise**

2.12 We understand that SE supports the implementation of the industry-led strategy in two principal areas:

- *growing and developing the business stock to “achieve a critical mass of companies of scale”* - supporting existing businesses in Scotland; attracting companies to Scotland; supporting new company creation and growth
- *exploiting Scotland’s key strengths which offer global advantage* – in (i) stem cells and regenerative medicine; and (ii) TCM.

2.13 In the brief for the present study, the client highlights five areas as crucial to realising the aims and objectives of the Life Sciences strategy:

- *people* : developing, attracting and retaining ‘talent’

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<sup>5</sup> See: <http://www.lifesciencesscotland.com/lss/lss-about/lss-lisab.htm> .

- *technology*: investing in innovation; streamlining commercialisation; “embedding company business activity in Scotland” – all mindful of long lead times to market and high attrition rates amongst Life Science businesses
- *financing*: attracting financial capital; addressing funding gaps
- *infrastructure*: to facilitate research and to meet specialist accommodation needs of Life Science businesses
- *collaboration*: collaborative working to attract businesses to Scotland; to increase scale and effectiveness of R&D; to enhance global competitiveness.

#### *Points of significance for this study*

- 2.14 The issue of ‘time to market’ is especially significant given the extended lead times associated with drug discovery and development: the Life Sciences strategy calls for an acknowledgement of extended lead times. There has emerged quite recently a much stronger, explicit interest amongst economic development bodies in the UK<sup>6</sup> in assessing factors such as time to first impact attributable to an intervention, time to maximum impact and subsequent rate of decay of impact. Intuitively (i.e. SQW’s conjecture), anticipated long lead times could make public sector interventions in support of certain Life Science initiatives relatively less attractive compared to other candidates for public sector support that may deliver impact more quickly.
- 2.15 The issue of inherently high attrition rates amongst commercialisation leads and prospects associated with TCM was raised in the course of this study. This would also imply relatively higher risk if ‘impact’ is to be measured only using parameters associated with business development and growth. A private sector risk investor would typically take a portfolio approach, looking to make substantial financial returns from a minority of investees in the portfolio which would more than compensate for under-performance or failure elsewhere.
- 2.16 However, there are likely to be different factors at work for different kinds of companies within the TCM value chain. Time to market and attrition rates are likely to be less important for CROs i.e. for specialist service providers, than those involved in the development of therapeutics. (We have developed no clear picture of the relative attrition rates on commercialisation leads and prospects for diagnostics companies.)

### Other recent research on TCM in Scotland

- 2.17 Deltjohn Limited was commissioned by SE in 2007 to report on the future of translational medicine in Scotland<sup>7</sup>. Much of its report provides recommendations for the development of the TMRC initiative and other matters of sector governance.
- 2.18 The report offers the following definition of ‘translational medicine’ (TM): “a complex science requiring input from many disciplines. It is the integrated application of innovative pharmacology tools, biomarkers, clinical methods, technologies and study designs to improve confidence in drug targets and drug candidates, understand the therapeutic index in humans, enhance cost effective decision making in exploratory development and increase Phase II success leading to a sustainable pipeline of new products.”

<sup>6</sup> Triggered in part by the PwC report in 2009 on the economic impact of England’s Regional Development Agencies.

<sup>7</sup> Deltjohn Ltd (2007) Scotland’s future in translational medicine. Draft report to SE.



- 2.19 The report identified strengths and weaknesses in the TMRC (and TMR Institute) initiative at that time:
- *strengths*: ownership by four universities and four Health Boards; established documentation and process for commissioning projects; established template for costing projects; financially stable; major partner (Wyeth) secured; generating IP for exploitation
  - *weaknesses*: joined-up vision not established; resource constrained; nine parties to any negotiation; not all universities and Health Boards included; only one major partner; expertise in IP exploitation and sector knowledge.
- 2.20 More broadly, the report identified the following as national strengths: Scotland's system of patient identification and world class clinical research capabilities (in CROs and NHS Health oriented companies).

#### *Points of significance for this study*

- 2.21 It is notable that the weakness associated with the inefficiency of conducting clinical trials has been addressed since the Deltjohn report. The NHS Research Scotland initiative has been established involving senior R&D management from the Scottish Health Boards and the Chief Scientist Office. Its work, intended among other things to facilitate the efficient conduct of clinical trials in NHS Scotland, has included the development of systems to enable prompt R&D approval of multi-centre clinical studies taking place in the NHS. This has included the establishment of the Permissions Co-ordinating Centre (NRS Permissions CC)<sup>8</sup> based in Aberdeen which offers a single point of contact for co-ordinating multi-centre studies.
- 2.22 The report's authors also made recommendations which to varying degrees have been advanced in the intervening period: (i) enhance the efficiency of analysis of patient records; (ii) improve approach to a bio-repository in order to optimise potential for both commercial and publicly-funded TM research; (iii) enhance university and NHS integration to make negotiations over future TM collaborations more effective.
- 2.23 Deltjohn also highlighted a number of company leads for SE/Scottish Development International (SDI) to follow up in the context of forming future TM collaborations.

## What is TCM?

- 2.24 Notwithstanding the useful definition of translational medicine provided by Deltjohn (see Para 2.18), from our exploratory desk research, it appeared that the term 'translational' was being used rather loosely and/or differently by different authors. Therefore, we asked consultees to define what TCM means to them and to indicate their own organisation's roles/objectives in advancing TCM. The following summarises the diverse responses:
- *'catch-all'* : TCM is used as catch-all phrase – "everyone uses it as they can get funding that way"
  - *contrasting perspectives*: there appear to be different perspectives in academia and industry

<sup>8</sup> See: [http://www.nhsgrampian.org/nhsgrampian/nrsPermissionsCC.jsp?pContentID=7170&p\\_applic=CCC&p\\_service=Content.show&](http://www.nhsgrampian.org/nhsgrampian/nrsPermissionsCC.jsp?pContentID=7170&p_applic=CCC&p_service=Content.show&)

- the academic view emphasises the concepts of ‘Bench to Bed’, ‘Pathway to Population’, ‘Molecule to Man’ (and back again in each instance)
- for pharma companies it means the activities associated with getting the drug to the patient
- *goal of patient benefit*: for a senior academic, TCM is about new research that will lead to benefit for patients
  - universities (and the NHS) can be viewed as the ‘owners of the pre-requisites’ which will make TCM happen (i.e. skilled staff, access to patients, access to tissue, patient records etc.)
  - research requires clinical material which can in this context mean ‘sick people’ and therefore a collaboration is required between the NHS and researchers to deliver the outcomes that will result in benefits to patients
- *developmental focus*: development of treatment and therapies – both with humans and animals
  - with a university’s objectives relating to research to benefit the community, a desire to be best in class internationally, and to contribute to health and wealth
- *discovery and assessment focus*: the identification of things that are measurable in humans that provide an indication of pathways to disease (both static and dynamic measurements). Also, the assessment of the impact of any interventions made in order to inform go/no go decisions prior to commencing large scale clinical trials.
  - alternatively, TCM includes all research taking new discovery from lab to humans, including animal work leading to clinical discovery, but not about ‘fundamental discovery’.

- 2.25 We have been led to understand that the term ‘translational’ may also be used with different meanings even within a single company.
- 2.26 Newby and Webb<sup>9</sup> pose the question: “What is translational research?” They confirm the views gathered during this study that the term continues to be used and interpreted in a range of ways, “usually reflecting the viewpoint of each observer”. These authors argue this “mirrors the continuum of the process from discovery of a basic scientific phenomenon all the way through to the widespread use of a healthcare innovation”.
- 2.27 Perhaps this response from one consultee captures the difficulty. How TCM is articulated depends on the audience: “for the principal of the university, TCM represents a fundamental part of medical/biological research and as such is a vital part of the university’s work, contributing to its international reputation – it is a key part of what Medical Schools are for. However, TCM also ‘presses financial buttons’ in terms of generating research grants and other income. If for a wider audience then the health and wealth outcomes of TCM are important to focus on”.

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<sup>9</sup> Newby and Webb (2010) Translational research: a priority for health and wealth. *Heart* vol. 96.11

- 2.28 A ‘policy’ perspective is provided in the Cooksey Report<sup>10</sup>: this states that translational research describes the work needed to bring an invention from pre-clinical into human trials. It identified two ‘gaps’ in what is termed the ‘critical path within UK health research’: an upstream gap associated with “pre-clinical development” and ‘early clinical trials’; and a downstream gap associated with the translation of clinical study findings into clinical/healthcare practice (the latter associated with “Health Technology Assessment”, “Health Services research” and “knowledge management”).

*Point of significance for this study*

- 2.29 Whilst the term ‘translational’ is used in a range of ways, it is in common currency in biomedical circles and its use is expanding into other research domains. It is less clear that the expression used in the brief for this study namely ‘translational *and* clinical medicine’ (our *emphasis*) is helpful. ‘Translational’ activity spans both pre-‘first in man’ investigations as well as post, i.e. can include pre-clinical and clinical studies, and should be used in this way with supplementary information on specific positioning. The business and economic challenges and opportunities for Scotland, in which SE may wish to play a further supporting role, should be ‘deconstructed’ into domains identified by Cooksey.

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<sup>10</sup> See [http://webarchive.nationalarchives.gov.uk/+/http://www.hm-treasury.gov.uk/d/pbr06\\_cooksey\\_final\\_report\\_636.pdf](http://webarchive.nationalarchives.gov.uk/+/http://www.hm-treasury.gov.uk/d/pbr06_cooksey_final_report_636.pdf)

## 3: Review of interventions

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- 3.1 In this section we present a summary review of five current interventions in support of TCM. This set of interventions, listed below, was specified in the brief for the study:
- Translational Medicine Research Collaboration (TMRC)
  - NHS Research Scotland Permissions Co-ordinating Centre (NRS Permissions CC)
  - Scottish Academic Health Sciences Collaboration (SAHSC)
  - Scottish Health Innovations Ltd (SHIL)
  - Edinburgh Bioquarter.
- 3.2 Most have been in receipt of financial support from SE although SE is not always the lead supporter: SE has supported the development of the SAHSC but not given funds directly to it. In addition to their diverse nature, the interventions are of quite different vintages: SHIL was set up in c. 2002 whereas the NRS Permissions CC began operating in only 2009 and Bioquarter has yet to have its first new tenant on site.
- 3.3 We have sought to characterise each intervention in terms of its associated inputs, activities, outcomes, outcomes and impact, i.e. its ‘logic model’. What we provide is our interpretation of documents describing each intervention provided by the client and/or descriptive information in the public domain.
- 3.4 These accounts are supplemented by a summary of views on each of the interventions from those consulted during this study. It is important to note that consultees were not selected as a statistically representative sample of beneficiaries of these interventions: they were selected through discussion with the client as a broad mix of individuals able to provide insights into wider TCM issues of relevance. In the absence of information directly from a sample of actual beneficiaries, what follows should not be regarded as a formal evaluation of the interventions discussed. For this, further primary research targeted on intended beneficiaries would be required.

### Translational Medicine Research Collaboration

- 3.5 The Translational Medicine Research Collaboration (TMRC) is a collaboration between four Scottish universities (Aberdeen, Dundee, Edinburgh and Glasgow), four NHS Health Boards (Lothian, Grampian, Greater Glasgow & Clyde and Tayside), Scottish Enterprise and the pharmaceutical company Pfizer (formerly with Wyeth).
- 3.6 The Translational Medicine Research Initiative (TMRI)<sup>11</sup> is the main delivery and exploitation vehicle for the TMRC. TMRI is a private limited company owned by Scottish Enterprise, the universities of Aberdeen, Dundee, Edinburgh and Glasgow and their associated NHS Health Boards.
- 3.7 Table 3.1 summarises our interpretation of the ‘logic model’ for TMRC.

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<sup>11</sup> See: <http://www.tmri.co.uk/about/>

Table 3.1: Summary of the logic model for TMRC

Step	Description	Evidence of targets and/or actuals – for Existing Interventions	Comment
Rationale	<p>Translational medicine provides an opportunity to reduce current bottlenecks in the development of new drug treatments [1]</p> <p>Benefits of attracting a global pharmaceutical company to Scotland to improve innovation and commercialisation of research: linking health and wealth for the benefit of Scotland. [1]</p> <p>Realise a ground-breaking collaborative venture in a new field of drug discovery and development, with the translational medicine approach resulting in the development of new therapeutics and new tests for the diagnosis and monitoring of human diseases.</p>	<p>The Brief [2] states that “Scotland’s competitive position in translational and clinical medicine has been validated by the attraction of a large scale collaboration with Wyeth (TMRC)”.</p>	<p>Implication is that TMRC provides an exemplar to be used to attract other investments</p>
Objectives	<ul style="list-style-type: none"> <li>to facilitate the translation of basic scientific and clinical expertise into effective therapeutics.</li> </ul> <p>The focus of the TMRC is [4]:</p> <ul style="list-style-type: none"> <li>selection of optimal molecular targets for the solution of significant unmet medical needs in all major disease areas.</li> <li>better understanding and quantification of compound-target interactions.</li> <li>improvement of safety through recognition and prevention of mechanistically related toxicity.</li> <li>development of innovative models and technologies to assess efficacy of compounds via biomarker discovery, validation and implementation.</li> <li>facilitation of optimal patient selection for clinical trials and personalised medicine.</li> </ul>	<p>Vision is to create a world class centre of excellence in biomarker discovery and utility. [3]</p> <p>Attraction of the TMRC is stated as being [2]:</p> <ul style="list-style-type: none"> <li>the perceived ease of doing business across a number of universities and health boards</li> <li>the quality of the clinical and academic research</li> <li>the nature of Scotland’s patient records.</li> </ul>	<p>The preferred corporate model to deliver the TMRC and maximise value for Scotland by capturing IP was to set up a private company limited by shares (TMRI Ltd), in which SE and the 5 Scottish research partners are shareholders. [1].</p>
Inputs	<p>Approval for projected expenditure for initial set up and operating costs of up to £17.54m (inclusive of VAT) over a 10 year period, towards a total investment of £159.7m[1]</p>	<p>R&amp;D expenditure by TMRI to total £96.1m between 2009/10 and 2015/16, with a further £21.9m in sunk costs</p> <p>Leverage: the SE investment over the appraisal period amounts to £27.8m and £34.4m if the sunk costs are also included. Leverage anticipated equates to: 1: 2.62 over 2009/10 – 2015/16 (1: 2.68 if sunk costs are included).</p>	
Outputs	<p>Development of new therapeutics and new tests for the diagnosis and monitoring of human diseases.</p> <p>The new Core Research Laboratory in Dundee was opened in April 2009, at a cost of £11.6m.</p>		
Outcomes	<p>Forecast revenue benefits:</p> <ul style="list-style-type: none"> <li>TMRI is expected to generate total revenue of £12.9m over the next seven years (£11.5m NPV).</li> </ul> <p>Significant benefits in terms of healthcare expected. Not quantified.</p>	<p>Additional, spillover benefits are expected from the presence of a global pharmaceutical company in Scotland.</p>	

Step	Description	Evidence of targets and/or actuals – for Existing Interventions	Comment
Impacts	<p>By April, 2009, over 100 high value jobs across the universities, NHS and at the core laboratory in Dundee had been created.</p> <p>Employment targets:</p> <ul style="list-style-type: none"> <li>for the period 2009/10 – 2015, forecast net employment is for 243 jobs per annum over the seven year appraisal period.</li> </ul> <p>Data on costs per job are also included in the report.</p>	During the initial appraisal [1] the economic analysis indicated that at the level of the Scottish economy, this project was expected to create and support around 96 additional jobs per annum and GVA of £38.6 million (at current prices) between 2006 and 2015.	There appears now to be a concern that this impact may not be realised.

#### *References cited for TMRC*

- [1] Translational Medicine Research Collaboration Approval Paper (Scottish Enterprise Board – SE (05)189)
- [2] SE Consultancy Support - Invitation to Quote: Translational and clinical Medicine Study (Scottish Enterprise 7<sup>th</sup> December 2009)
- [3] Translational Medicine Research Collaboration (/www.tmr.co.uk/about-us/what-is-the-tmr)
- [4] Translational Medicine Research Collaboration (www.tmr.co.uk/faqs)
- [5] Scottish Enterprise News (21<sup>st</sup> May 2009). 'First Minister opens latest landmark on Scotland's intellectual frontier. See: [www.scottish-enterprise.com/sedotcom\\_home/about-us/se-whatwedo/news-se-about-us/news-se-about-us-details.htm?articleid=274090](http://www.scottish-enterprise.com/sedotcom_home/about-us/se-whatwedo/news-se-about-us/news-se-about-us-details.htm?articleid=274090).

3.8 We understand that the status of the TMRC and the performance of the TMRI have been assessed by Scottish Enterprise. The key learning points shared with SQW during this study include:

- future research collaborations should have a clear statement of expected outcomes and impacts along with a robust business plan to realise economic benefit to Scotland
- the experience Scotland has accrued in developing and delivering TMRC should be retained and used for future collaborations
- although individual collaborators will have different scientific requirements, common features of future collaborations are likely to include
  - simple and easy governance
  - professional contracting and delivery
  - a common understanding of objectives
  - opportunities for all parties to leverage additional funding.

#### *Points of significance for this study*

3.9 A key objective of the Life Science Strategy (2008) is to attract inward investment from global pharma companies. This objective is viewed as contributing to a competitive medical healthcare platform in Scotland at several levels:

- firstly, the presence of a global pharma will bring direct economic benefit in terms of inward investment and resulting direct employment, and will help attain a critical mass in clinical/ medical sciences across Scotland
  - secondly, it offers the opportunity to create greater collaborative ties (at close geographical proximity) between pharma, universities and the NHS through integrated R&D programmes, and to permit easy access to shared facilities, services, data, samples and patients in the case of clinical trials
  - finally, the presence of major pharma companies is seen as enabling a ‘thickening’ of the labour market, providing more diverse career pathways and enhancing retention of high value jobs within Scotland.
- 3.10 Linked to the objective of attracting inward investment, is the recognition of the need to reduce bottlenecks along the innovation pipeline (from R&D through to commercialisation)<sup>12</sup> and to gain competitive advantage through an acceleration of products to market.
- 3.11 From the evidence it appears that the TMRC has successfully delivered the desired inputs and research-related activities. The evidence available to us does not permit assessment of the volume, quality and ‘market’ significance of research outputs from TMRC to date. It is the linkage between these research outputs and consequent business outcomes for: (i) primarily, the current industry partner; (ii) indigenous suppliers of specialist services (i.e. CROs); and (iii) other indigenous companies (new or existing) participating in knowledge exchange and commercialisation of IP, that sustained and growing economic impact will be realised. The link in the logic model between translational research outputs and business outcomes (by type of business) is crucial here and merits close, real-time evaluation by SE given the scale of investment and the high profile associated with the TMRC/TMRI initiative.
- 3.12 Also, given the importance accorded to this collaborative university/NHS/inward investor model as an exemplar to attract other major companies, it is crucial for the future that SE and its partners exploit to the full the learning that has come from the TMRC/TMRI experience. Recalling the Deltjohn report’s comment on the weakness of the TMRC in having “nine parties to any negotiation”, it will be important to monitor if the recently formed SAHSC is successful over time in mitigating the risks of complex partnership working.

### ***Routes to potential economic impact***

- 3.13 For SE in the context of its current strategy, the economic impact from an initiative such as TMRC comes from the initial investment made and then the sustained presence in Scotland by an inward investor (pharma company), employing staff in Scotland and purchasing goods and services from a supply chain in Scotland. Investment from this same source in R&D within the Scottish research-base of course also creates and/or sustains employment, but not directly in businesses in Scotland.
- 3.14 For this and for all the other TCM-related interventions reviewed in this Section, we offer our ‘from first principles’ assessment of routes to potential economic outcomes and impact. We restrict this specifically to routes to growth through the business base (as distinct from safeguarding or creating employment in the university sector or the NHS):

<sup>12</sup> In pharmaceutical drug development, this process encapsulates the phases between drug discovery through to formalised patient treatment, colloquially termed ‘from bench to bedside.’



- the translational research activity leads to the commissioning of work from CROs based in Scotland (e.g. for pre-clinical studies or early stage clinical trials)
- the research leads to Intellectual Property (IP) which is exploited successfully by the inward investor (by the pharma company) directly, which leads to its sustained and perhaps growing business presence in Scotland
- the research leads to the development of IP which is licensed to Scottish companies which go on to exploit it successfully and grow their business in Scotland as a result
- the research leads to the development of IP that is exploited through the establishment of spin-out companies which go on to exploit it successfully and grow a business in Scotland as a result.

3.15 All four routes depend on the scale, quality and timing of the commercialisation of the translational research output. Issues of take-up and efficacy of SE's generic processes and 'products' in support of commercialisation are therefore relevant here. The latter two routes also depend on the ownership of the IP and the interests and policies on exploitation of the pharma company partner (on its corporate policy or model for innovation). It is important to note that in business terms, the R&D is one *input* to business development.

## NHS Research Scotland Permissions Co-ordinating Centre

3.16 Currently, all clinical research within NHS Scotland undergoes a process of NHS R&D management approval to ensure the research meets all necessary ethical, governance and regulatory requirements,. This process also includes costing and the set-up of legal contracts. The NHS Research Scotland Permissions Co-ordinating Centre (NRS Permissions CC) was established in 2009 as a single point of contact in Scotland for commercial and non-commercial researchers: it aims to enhance efficiency by removing time-consuming duplication of procedures associated with multi-centre clinical research studies. The Health Boards continue to have responsibility for granting approvals: the NRS Permissions CC oversees the co-ordination of the procedures for multi-centre trials.

Table 3-2: Summary of the logic model for the NHS Research Scotland Permissions Co-ordinating Centre

Step	Description	Evidence of Actuals – Interventions	Targets and/or Existing	Comment
Rationale	In a globally competitive market, there is a need to simplify and speed up the approval process for research activities (e.g. clinical studies). This will enhance the attractiveness of Scotland as a site for large scale research projects and trials [1]  The CRO and pharma industry had no single point of contact with NHS Scotland and were forced to work with individual Health Boards. There was demand from non-commercial and commercial parties for a one-stop-shop dealing with multi-centre clinical research approval in Scotland. [3]	The Brief [2] states that: "Scotland's competitive position in translational and clinical medicine has been validated by the attraction of a large scale collaboration with Wyeth (TMRC)."		The NRS network was established in 2008 covering the 14 NHS Health Boards across Scotland [1]. NRS Permissions CC is only one initiative to come from the NRS collaboration.
Objectives	<ul style="list-style-type: none"> <li>• to provide a single, centralised point of contact for those wishing to conduct multicentre clinical research - both non-commercial and commercial - within Scotland.</li> </ul>	NRS Permissions CC sets out a number of specific, measurable and time-bound objectives that can be monitored and evaluated over time.  Note: the NRS Permissions CC co-		It is notable that the objectives include both activity/efficiency objectives plus ones relating to

Step	Description	Evidence of Actuals – Interventions	Targets and/or Existing	Comment
	<p>The focus of its development from the outset includes [3]:</p> <ul style="list-style-type: none"> <li>• develop a functioning Scotland-wide system for governance of approval and project management over the first 4 months of operation</li> <li>• achieve rapid study approval times - target 60 day approval for 90% of all studies within 1 year (average for UK was 173 days in 2007 ABPI figures)</li> <li>• negotiate and manage key commercial clinical research opportunities for Scotland</li> <li>• market NRS Permissions CC internally to NHS Scotland</li> <li>• gain 3 fold increase in number of multicentre commercial studies in Scotland over the first 3 years from a baseline of 24 per annum</li> <li>• increase the turnover from commercial trials in Scotland by at least 50% over three years, from a baseline of £7m to £11m</li> <li>• raise awareness across the industry of Scotland as a first choice destination for commercial research.</li> </ul>	ordinates the approvals work conducted within the Health Boards: it does not undertake the approvals work itself.		growth in scale of activity and revenue.
Inputs	<p>The Centre opened in Aberdeen for commercial and non-commercial business in April and May 2009, respectively. [1]</p> <p>Project funding sources at time of approval [3]:</p> <ul style="list-style-type: none"> <li>• £279k from the CSO</li> <li>• £190k Scottish Enterprise</li> </ul>			The NRS Permissions CC is only one initiative to arise from wider NRS collaboration.
Outputs	<p>NRS Permissions CC current focus is on [1]:</p> <ul style="list-style-type: none"> <li>• coordinated approvals for multi-centre trials</li> <li>• Best Practice procedures for multi-centre R&amp;D permission across NHS Health Boards</li> <li>• working to improve R&amp;D permission times</li> <li>• performance monitoring and analysis</li> <li>• promotional material on achievements, services and benefits</li> <li>• links with equivalent centralised offices in England and Wales to streamline the R&amp;D permission process for UK- wide projects</li> <li>• register of clinical researchers in Scotland</li> </ul>	<p>NRS Permissions CC outputs [1]:</p> <ul style="list-style-type: none"> <li>• for non-commercial activity - 556 Scottish Health Board multicentre project approvals were granted between Feb '08 – Aug '09. Median approval time 31 working days</li> <li>• for commercial activity – during May '09 – Dec 09, coordinated 21 multicentre projects (equating to 33 Scottish Health Board approvals). Median approval time 21 working days (89% approvals within 60 days)</li> </ul> <p>NRS Permissions CC aims to achieve 95% of R&amp;D approvals within 30 days by June 2010.</p>		Non-commercial business approvals has a 1 year pilot prior to the launch of the commercial business approval process in April 2009 [3]
Outcomes	<p>This approach will enhance the attractiveness of NHS Scotland as a site for large scale research projects [1]. It will bring more trials to Scotland.</p>	<ul style="list-style-type: none"> <li>• 3 fold increase in the number of multicentre commercial studies in Scotland over the first 3 years of operation from a baseline of 24 per annum</li> <li>• increase the turnover from</li> </ul>		It is not possible directly to translate these figures into businesses benefit specifically for

Step	Description	Evidence of Actuals – Targets for Interventions	and/or Existing Comment
		commercial trials in Scotland by at least 50% over three years, from a baseline of £7m to £11m.	indigenous CROs. It is assumed that the turnover relates to NHS turnover.
Impacts	Increase in trials undertaken in Scotland will bring revenue to the NHS with benefits through support for employment as well as any subsequent health benefits.	Increased interest in undertaking trials in Scotland will bring increased business opportunities for indigenous CROs with, upon successful tendering, an impact on turnover and employment. The nature of this potential impact is not quantified in documents reviewed for this study.	

*References cited for NRS Permissions CC*

- [1] NHS Research Scotland Permissions Coordinating Centre (<http://www.nhsgrampian.org/nhsgrampian/nrsPermissionsCC>)
- [2] SE Consultancy Support - Invitation to Quote: Translational and clinical Medicine Study (Scottish Enterprise 7<sup>th</sup> December 2009).
- [3] NHS Research Scotland Approval form (27 January 2009).

- 3.17 The aims to reduce administration time, avoid duplication and provide a uniform service are highly desirable. The NRS Permissions CC has been established for less than a year. However, we understand that the NRS collaboration began to address this issue c. 1 year prior to the launch of the Permissions CC. It is too early to assess the impact of the Permissions CC in its own right, but the figures published on its web site for reduced approval times certainly appear to point to good progress in improving against the current standard of 60 days.

*Points of significance for this study*

- 3.18 Improvements in process brought about by the NRS Permissions CC will have a beneficial impact on pharma and CROs wishing to undertake clinical trials: they will make Scotland a more attractive location in which to undertake trials, complementing other attractors such as the quality of patient records.
- 3.19 Of course, the benefits of the improved process may ‘leak’ beyond the Scottish business-base and economy to the extent that a share of any attributable increase in trials activity goes to CROs without a Scottish base.
- 3.20 A number of other issues arise. Whilst the work of the NRS Permissions CC to achieve efficiency gains in R&D approval times is relevant, it is arguably a benefit which in a globally competitive market soon becomes a ‘hygiene factor’ - something that is expected and quickly taken for granted in the market. For significant, sustained growth it is, arguably, the NRS Permissions CC’s objectives associated with gaining a three-fold increase in the number of multicentre commercial studies and increasing the turnover from commercial trials by at least 50% over three years that are important. It is not clear from the documents we have reviewed if it is envisaged that growth will come from improved efficiency of process alone. Also, assuming the turnover is that associated with revenue to the NHS, the growth targets give no sense of the scale of trials activity likely to be captured by CROs who employ staff in Scotland.

- 3.21 Additional net business benefit to Scotland only accrues if CROs based in Scotland gain a substantial share of the expanding trials activities that the NRS Permissions CC aims to bring about. There would be merit in SE working with the NRS Permissions CC to ensure tracking mechanisms are in place not only for progress towards this increase in trials activity, but specifically the share of this that is won by CROs with a base in Scotland.
- 3.22 Also, as indicated elsewhere in this report:
- the attractiveness of Scotland for trials may not always be differentiated by commissioning companies from the status of the UK overall as a location
  - there are polarised views on the extent to which capacity in the NHS is a serious constraint on the future growth of trials activity in Scotland
  - notwithstanding the NRS Permissions CC's work, there is a view expressed by senior staff associated with the NHS R&D function, that the scope for growth in multi-centre trials in Scotland is "not substantial".
- 3.23 Given all the above, the first priority for SE would seem to be to ensure that the business environment in Scotland remains attractive to the existing CROs in the business-base. Whatever the NRS Permissions CC achieves in terms of enabling growth, it does seem that its drive towards process efficiency contributes to this priority.

### ***Routes to economic impact***

- 3.24 The routes to potential economic outcomes and impact based on a 'from first principles' assessment of the NRS Permissions CC are as follows:
- as a result of the efforts of the NRS Permissions CC, more trials are conducted in Scotland by companies with no base in Scotland – this provides an additional revenue stream to the NHS and other purchasing may benefit suppliers in Scotland
  - more trials are conducted in Scotland which are undertaken by CROs with a base in Scotland – in addition to NHS revenue, the CROs in Scotland benefit from increased business
  - because of the improved efficiency brought about by the NRS Permissions CC, those CROs presently with a base in Scotland find it attractive to sustain their presence here
  - given that more trials are conducted in Scotland, CROs with no current presence here, decide to locate a business unit in Scotland
  - the efficiency of the processes co-ordinated by NRS Permissions CC adds to the attractiveness of Scotland for inward investment in translational research by global pharma.

## **Scottish Academic Health Sciences Collaboration**

- 3.25 The Scottish Academic Health Sciences Collaboration (SAHSC) is a partnership established to coordinate and accelerate R&D in translational medicine. Its purpose is to support joint NHS/university opportunities that are pan-Scotland. It complements the collaboration established through the formation of NHS Research Scotland.

- 3.26 The SAHSC partnership brings together NHS Health Boards and the university medical schools in Aberdeen, Dundee, Edinburgh and Glasgow. SAHSC aims to facilitate closer integration between these organisations and enable Scotland to compete more effectively for UK Government funding for translational research, including experimental medicine and clinical trials, as well as creating partnerships with industry.<sup>13</sup>

Table 3-3: Summary of the logic model for the Scottish Academic Health Sciences Collaboration

Step	Description	Evidence of Targets and/or Actuals – for Existing Interventions	Comment
Rationale	SAHSC formed in order to establish a world-leading clinical research platform; to provide a single point of contact for pharmaceutical and biotech companies to develop translational medicine through “bench to bedside” research programmes; and to speed up the development of drugs in collaboration with university medical schools and clinicians in the NHS.		The reference to time related benefits is notable
Objectives	<p>SAHSC’s programmes will help to develop the latest scientific medical research and speed up its delivery to patients through clinical trials in order to develop new drugs and treatments. [1]</p> <p>The stated aims of the SAHSC are also [1]:</p> <ul style="list-style-type: none"> <li>to create a world leading platform to attract research funds from government, charity and commercial sources</li> <li>to facilitate leadership of an evidence-based culture of change in the NHS</li> <li>to be an engine for economic development through the generation of high value jobs and exploitation of intellectual property.</li> </ul>	Elements of these objectives of particular relevance to SE would seem to be: attracting funds from commercial sources (especially inward investors); contributing to the generation of jobs (especially if in the business base); and exploitation of IP (especially if exploited by firms with a base in Scotland).	According to the SAHSC [4] the NRS Permissions CC is “integral to the SAHSC” and will provide a harmonised and streamlined system for contracting and costing of clinical studies.
Inputs	<p>The SAHSC will [2]:</p> <ul style="list-style-type: none"> <li>invest in NHS research infrastructure in areas such as scanning capability, tissue banking and research nurse support.</li> </ul> <p>By 2011/12, the collaboration is expected to deliver [5] :</p> <ul style="list-style-type: none"> <li>an increase in funding awards from MRC and NIHR by circa £30m pa.</li> </ul>	The major financial input to the SAHSC is £10 million from the Scottish Government’s Chief Scientist Office.	
Outputs	<p>By 2011/12, the collaboration is expected to deliver [5] :</p> <ul style="list-style-type: none"> <li>a 50% increase in the number of Scottish patients volunteering for clinical trials and studies</li> </ul> <p>In addition, SAHSC aims to:</p> <ul style="list-style-type: none"> <li>offer a co-ordinated system for contracting and costing of research across Scotland</li> <li>provide a Scotland-wide investment in research-related IT capacity.</li> </ul>		

<sup>13</sup> Scottish Academic Health Sciences Collaboration Proposal (Briefing Note: 18<sup>th</sup> December 2008)

Step	Description	Evidence of Targets and/or Actuals – for Existing Interventions	Comment
Outcomes	<p>Reversal in Scotland of the UK-wide trend of decline in pharma and biotech spend on clinical trials and studies.</p> <p>A (single?) new strategic partnership with a major pharma company.</p> <p>Faster development of drugs through collaboration between university medical schools and clinicians in the NHS.</p>	<p>Measure of relevance to SE - at least one new partnership with a pharma company.</p> <p>Faster development if it leads to faster commercialisation which brings business benefit to firms with a base in Scotland.</p>	<p>The reference to spend on trials etc. seems to link to the targets for trials referred to in documents for the NRS Permissions CC (see above).</p>
Impacts	<p>Generation of 250 multi-disciplinary jobs across partners in the NHS to support clinical research, ranging from radiologists, pharmacy support and clinical nurses. [4].</p> <p>GVA from creation of the new jobs</p>		<p>The employment impact at least directly, and initially, is not in the business base.</p>

#### References cited for SAHSC

- [1] SE Consultancy Support - Invitation to Quote: Translational and Clinical Medicine Study (Scottish Enterprise 7<sup>th</sup> December 2009).
- [2] Life Sciences Scotland: The Scottish Academic Health Sciences Collaboration (SAHSC) (<http://www.lifesciencesscotland.com/lss/lss-solutions/lss-collaborative-partnerships.htm>)
- [3] The Scottish Government News (10<sup>th</sup> March 2009). ‘Academic health sciences collaboration’. (<http://www.scotland.gov.uk/News/Releases/2009/03/16100805>)
- [4] Scottish Academic Health Sciences Collaboration: A World Leading Clinical Platform for Patient Orientated Research (Scottish Government Launch brochure, June 2009)
- [5] Scottish Academic Health Sciences Collaboration Proposal (Briefing Note: 18th December 2008)

- 3.27 SAHSC is a strategic initiative to bring together organisations which aims *inter alia* to be “an engine for economic development through the .... exploitation of intellectual property”. Its launch brochure [4] sets out to demonstrate the critical mass, capabilities and therapeutic specialisms within Scotland and how individual initiatives within Scotland fit together.
- 3.28 This is a major initiative established only in June 2009. In seeking to create a “world leading platform” to attract research funds from government, charity and commercial sources, the formation of SAHSC is seen as representing a major boost in clinical research capacity, helping Scotland to attract funds for patient-oriented research. In turn, so the argument goes, this will facilitate further investment and economic development benefits for Scotland, as well as contributing to ongoing improvements within the NHS in Scotland.
- 3.29 The SAHSC coordinates resources to support local and national capabilities in informatics, clinical records and e-Health, and to create additional capacity associated with tissue biorepositories and disease biomarker identification. These capabilities are seen as fundamental to underpin a single translational medicine platform within Scotland for academics and industry alike.

#### Points of significance for this study

- 3.30 The objectives of the SAHSC and the capability and capacity within the Scottish research and healthcare ‘system’ upon which it builds are the critical underpinning of Scotland’s aspirations in Life Sciences. Attracting investment in translational research and related trials from funding

sources outside Scotland (commercial or public) contributes to the Scottish economy by creating/sustaining high value research jobs. Impact directly on the Scottish business base, arguably now a prime focus of SE's interests, is less directly assured.

3.31 Although it is too early in the life of the SAHSC to evaluate its economic development impact, our review of documents relating to the initiative raises a number of issues:

- the role of collaboration and associated engagement with commercial investors in translational research is not new (cf. TMRC): it is not clear what will be different substantively through the SAHSC model beyond, arguably, matters of 'internal' governance
- it is not self-evident that changes in governance specifically will lead to enhanced commercialisation and economic impact beyond what TMRC/TMRI is achieving.

3.32 The benefits of learning from prior experience and the impetus provided by the SAHSC to TCM in Scotland will become evident over time. It will be important to ensure that the achievements of the SAHSC in building a world-leading clinical research platform include an effective mechanism to promote and support IP exploitation.

### ***Routes to economic impact***

3.33 In addition to the (important) potential introduction to the Scottish labour market of research trained Life Scientists, the routes to potential economic outcomes and impact based on a 'from first principles' assessment of the SAHSC, in terms relevant now to SE, are as follows:

- the translational research activity attracted by the SAHSC leads to the commissioning of work from CROs based in Scotland (e.g. for pre-clinical and other early stage trials)
- the translational research activity that is funded by an inward investor (by a pharma company) attracted by the SAHSC is accompanied by the investor establishing a project team/ business unit in Scotland
- the translational research leads to IP which is exploited successfully by the inward investor (by the pharma company) directly, leading to sustained and perhaps a growing business presence in Scotland
- the translational research leads to the development of IP which is licensed to Scottish companies which go on to exploit it successfully, and grow their business in Scotland as a result
- the translational research leads to the development of IP which is exploited through the establishment of spin-out companies which go on to exploit it successfully, and grow a business in Scotland as a result.

3.34 At the level of investigation into the SAHSC undertaken in the present study, the routes to economic impact, especially ones involving businesses operating in Scotland, appear to be similar to those envisaged for TMRC. However different the governance arrangements may be, it will be important for SE to establish whether the prospects for the kind of economic impact it wishes to see delivered through SAHSC are likely to be any different in terms of route and/or scale to that in prospect from TMRC.



## Scottish Health Innovations Ltd.

- 3.35 The brief for this study also included a review of SHIL. This company provides professional/commercial services to NHS Scotland to support the commercialisation of staff 'ideas' and inventions: it assesses commercial potential; where relevant, applies for protection on behalf of inventors and their health board; and may assist in product/service development by bringing in other specialists, providing development funding, and identifying markets and business partners to support market entry.
- 3.36 Notwithstanding its inclusion in this study, on the basis that SHIL appears in part to be focused on NHS 'inventions' rather than on 'research', it is arguable that its role may in part lie outside what is generally considered to be translational activity. However, case studies provided on the SHIL web site do indicate the role it plays in supporting clinical trials for devices being developed by its clients.
- 3.37 The review of SHIL draws on the company's Annual Report for 2009.

Table 3-4: Summary of the logic model for SHIL

Step	Description	Evidence of Targets and/or Actuals – for Existing Interventions	Comment
Rationale	Healthcare professionals within NHS Scotland have innovative ideas and inventions that are relevant to enhanced healthcare delivery and have commercial value, but for optimal development and protection they require specialist support.		
Objectives	Working in partnership with NHS Scotland, SHIL has the objectives of identifying, protecting and helping to develop new ideas that come from healthcare professionals.  SHIL also offers commercial opportunities to businesses interested in developing NHS innovations.		We understand that the exploitation of research output of staff with joint university/NHS appointments may be handled by the associated university.
Inputs	Financial: <ul style="list-style-type: none"> <li>'core' grant income from ERDF, Public Sector Research Exploitation (PSRE) fund; Chief Scientist Office and NHS Scotland; SE and HIE</li> <li>project specific grants</li> <li>commercial income – from royalties and consultancy</li> </ul> Ideas disclosed to SHIL: <ul style="list-style-type: none"> <li>2007-8: 71</li> <li>2008-9: 189</li> </ul>	The number of disclosures can be regarded as an 'outcome' of SHIL's own marketing activity within the NHS.	
Outputs	The following are reported: <ul style="list-style-type: none"> <li>a programme of events for staff in NHS Health Boards</li> <li>outputs from regulatory consultancy projects</li> <li>IP audits</li> <li>protection for IP</li> <li>to date, 42 commercial projects</li> </ul>		

Step	Description	Evidence of Targets and/or Actuals – for Existing Interventions	Comment
	completed		
Outcomes	<p>Of the projects completed to date: 16 are licensed to a manufacturer; 2 are being sold directly by SHIL.</p> <p>Five spin-outs have been formed and four more are in the pipeline.</p> <p>Direct sales of Class 11a medical devices.</p>	SHIL is seeking licence partners for another 19 completed projects.	<p>We understand that royalty income from licensing although presently low is due to increase year on year. Also, first income from direct sale of product was achieved in 2009.</p>
Impact	<p>Not specified in documents reviewed. Will come from turnover and employment associated with exploitation by firms in Scotland in receipt of support from SHIL.</p> <p>The NHS may also obtain a revenue stream from royalties.</p>	<p>In 2009 SHIL reported an increase in its own staff, albeit supporting largely from public funds.</p> <p>It reported its contribution to the establishment of 5 spin-out companies and provided profiles of the work of 4 of them (Lumicure, B1 Medical; Cardioprecision and Touch Bionics).</p> <p>The Touch Bionics web site states: "In early 2003, the company was spun out from the National Health System, .... and became the first SHIL spin-out to receive significant funding."</p>	<p>In April 2010, Touch Bionics won the Queen's Award for Innovation.</p> <p>The Touch Bionics web site points to a business impact attributable in part at least to SHIL.</p>

*Reference cited for SHIL*

SHIL Annual Report, 2009

- 3.38 The key element in this intervention is its focus on the identification, protection and exploitation of ideas and inventions. Although working for the benefit of the NHS in Scotland, its approach seems firmly commercially oriented. To this degree, it arguably positioned more fully in that place in the landscape that is SE's immediate concern – the creation of sustainable businesses through support for innovation, assuming that the business prospects supported by SHIL also have growth potential.

*Point of significance for this study*

- 3.39 In the absence of comprehensive and independent evaluation evidence, it is not possible here to be definitive about the efficacy of the SHIL approach, nor about scale and sustainability of its impact. However, the reported outcomes in terms of product sales, IP for licensing and track record on spin-outs created to date appear *on the face of it* to be valuable contributions: however, it remains highly dependent on financial support from the public sector. It certainly appears as if SHIL is demonstrating a capability to deliver tangible commercialisation outcomes: it is not possible without primary research with beneficiaries to ascertain the degree to which any business and economic impact is directly attributable to SHIL, but the acknowledgement of its role by Touch Bionics (see table above) is notable.

## **Routes to economic impact**

- 3.40 In addition to direct benefits to healthcare in Scotland, the routes to potential economic outcomes and impact based on a ‘from first principles’ assessment of SHIL are as follows:
- licensing of IP based on NHS inventions to companies outside Scotland who pay royalties to SHIL/NHS Health Boards which are then ‘re-cycled’ into the Scottish economy
  - licensing of IP to companies based in Scotland which go on to exploit it successfully, and grow their business in Scotland as a result
  - exploitation of IP through the establishment of spin-out companies which go on to exploit it successfully, and grow a business in Scotland as a result.
- 3.41 Given the term over which SHIL has been in receipt of public sector support, it is almost inevitable that questions concerning exit strategies for certain public sector funders will be raised. It is unlikely that market failures associated with proving-up and taking forward to market NHS inventions will have been ‘cured’ by now and it seems clear from SHIL’s 2009 Annual Report that it is far from being self-sustaining on the back of commercial revenue generation.
- 3.42 It would appear that SHIL is operating at a position that is highly relevant to SE in the short to medium term, albeit working with only a sub-set of commercialisation opportunities and possibly not those that may emerge from translational research. For this reason, there should be a strong interest in SE in determining the scale of net added value it is achieving from empirical evidence and in assessing the likely sustainability and scope for up-scaling of its operation and outputs.

## **Edinburgh Bioquarter**

- 3.43 Bioquarter is the least mature of the interventions under consideration, albeit a key intervention by SE in the Life Sciences sector relevant to TCM. Because of this, it is the initiative for which we have least evidence on outcomes and impact to draw on. The ‘logic model’ is based on public domain information associated with marketing of Bioquarter plus summary information provided to us by the client. This section is supplemented by information from a recent press release on the decision by the drug development company TPP Global Development to establish an operation on the Bioquarter site.

**Table 3-5: Summary of the logic model for Bioquarter**

<b>Step</b>	<b>Description</b>	<b>Evidence of Targets and/or Actuals – for Existing Interventions</b>	<b>Comment</b>
Rationale	The development of a high quality site for Life Science businesses adjacent to a major teaching hospital and centres of medical research excellence will establish Scotland as a world class location for translational medicine and the commercialisation of biomedical research and technology, attractive to inward investors.		Bioquarter is a collaboration with the University of Edinburgh (UoE), the NHS and the private sector, including SE’s commercial development partner Alexandria Real Estate Equities, Inc (ARE).

Step	Description	Evidence of Targets and/or Actuals – for Existing Interventions	Comment
Objectives	<ul style="list-style-type: none"> <li>attract world-class Life Sciences companies and individual scientists to Scotland</li> <li>stimulate interaction between clinical, commercial and academic experts</li> <li>boost the rate of formation and growth of science and technology ventures</li> <li>generate on-site investment and provide accommodation for employment</li> <li>create net additional employment impact at the Scottish level</li> <li>create net GVA impact</li> </ul>		
Inputs	<ul style="list-style-type: none"> <li>investment of c.£600m</li> <li>inputs from partners: SE/SDI, University of Edinburgh, NHS Lothian, the City of Edinburgh Council and Alexandria Real Estate Equities, Inc.</li> </ul>	<ul style="list-style-type: none"> <li>to generate 1.4 million square feet of biomedical and R&amp;D facilities, including 900k square feet of accommodation for commercial use.</li> </ul>	
Activities	<p>The project has four major component parts: investment in Enabling Infrastructure; Scottish Centre for Regenerative Medicine (SCRM); Commercialisation and a BioIncubator - each with associated objectives.</p> <p>There is reference to activities undertaken by the Bioquarter partners and ones planned in support of Bioquarter tenants:</p> <ul style="list-style-type: none"> <li>conduct of translational research</li> <li>incubation support for new businesses</li> <li>other business development and mentoring support including services in support of international trade</li> <li>provision of financial assistance</li> <li>development of inter-disciplinary partnerships</li> <li>access to pre-clinical testing facilities, clinical trials support</li> <li>infrastructure management</li> <li>conferences/meetings on site</li> </ul>		
Outputs	<p>For the period from 2004-2006: land acquisition and initial phase of enabling infrastructure.</p> <p>Outputs of the following kinds have been reported to date: land acquisition and site infrastructure development; development of the SCRM and Commercialisation Programme; Joint Venture agreement with a property developer; recruitment to key posts; development lab facilities operational.</p> <p>The first commercial building is due to open in early in 2012.</p>	<p>More detail on the intended outputs and outcomes for each of the four components of the Bioquarter initiative is provided in Para 3.44.</p>	
Outcomes	<ul style="list-style-type: none"> <li>key types of outcomes identified include: private investment in Bioquarter; spin-out and start-up companies; growth in trials activity. For more detail see Para 3.45.</li> </ul>	<p>One important potential source of incubatees will be spin-outs from the co-located research centres (and possibly also firms spawned from NHS staff inventions).</p>	

Step	Description	Evidence of Targets and/or Actuals – for Existing Interventions	Comment
Impact	<p>The public domain information indicates a baseline of 1,200 researchers on “the existing Bioquarter site”: most will be university and NHS employees.</p> <p>The stated objectives of the four component parts make some reference to accommodating additional jobs (e.g. private sector jobs associated with the Bio-Incubator). However, we understand that SE is in the process of updating previous appraisals of the Bioquarter project to provide one overall assessment of the project encompassing all elements which presumably will include forecasts of additional employment and GVA impact.</p>	The formal approval to acquire land for the project and support infrastructure delivery was given by the SE Board in 2004: this approval indicated that the project would be likely to take 25 years for the vision to be delivered in full.	Depending on how ‘success’ is to be measured, the partitioning of employment impact between university, NHS and commercial employment will be important.

3.44 Further information on the outputs and outcomes associated with the objectives of each the four components of the Bioquarter project is provide below:

- *Enabling infrastructure:*
  - land for the development of 51,000m<sup>2</sup> of academic and health service-related research space by the UoE and NHS.
  - land for the development of up to 82,450m<sup>2</sup> of commercial space.
  - private sector investment (JV partner) to facilitate the development of buildings for commercial Life Science tenants in a high quality campus development.
  - up to 110,000m<sup>2</sup> of longer term expansion potential in the form of un-serviced land
- *SCRM:*
  - create a world leading centre for excellence in stem cell research
  - high quality accommodation for c. 220 leading researchers and ancillary commercial space.
  - integral high quality (GMP) stem cell manufacturing facility.
  - accommodate commercial Life Sciences entities with the objective of stimulating the supply chain relating to stem cell therapies.
- *Commercialisation:*
  - create 18 additional spin-out/start-up companies after 7 years.
  - win at least 10 additional clinical trials and 25 additional translational trials over 5 years.
  - increase license sales from £240k to £1.1m and engage in at least 20 new collaborative relationships

- attract at least 1 long term major pharmaceutical company collaboration (employing more than 50 FTE) within 5 years
- create a legacy impact to establish a culture of entrepreneurialism in the research community at Little France
- *BioIncubator:*
  - c. 8,500 sq m of laboratory and office accommodation for commercial Life Sciences tenants (or the NHS) by 2012
  - accommodate over 100 net FTE additional jobs by 2016.
  - specialist incubation space within the facility for early stage Life Sciences companies and an associated world-class entrepreneurial support service.
  - multi occupancy space within the facility to accommodate the ‘grow on’ requirements of a number of fast growing commercial Life Sciences tenants.

#### *Points of significance for this study*

- 3.45 Bioquarter is promoted as a “landmark Life Science hub” that establishes Edinburgh and Scotland as “one of the world’s top ten centres for biomedical commercialisation”. With undoubted potential, we would argue that the commercialisation claim for Bioquarter can at this stage only be an assertion, an aspiration: its commercialisation credentials are yet to be proven.
- 3.46 The University of Edinburgh’s track record in spawning spin-out and start-up companies is reported by its Research and Innovation office<sup>14</sup>. In the five years from 2004-5 to 2008-9 the University took a stake in 17 spin-outs and supported 86 start-up companies: company formation in the Life Sciences is not reported specifically. The University estimates that c. 87% of these firms are still active in some form, employ c. 350 staff and have raised over £70m in investment funding. Since the first company formed in 1967, three spin-outs have become public listed companies, all associated with electronics. The aspiration for Bioquarter must be to improve on the existing record in terms of numbers of Life Science companies formed, but more importantly to lead to the formation of sustainable, high growth companies incubated and growing on in Bioquarter.
- 3.47 Significantly, many of the licensing opportunities listed on the Research and Innovation office web site are associated with biomedical science and technology<sup>15</sup>. Technology licensing occurs of course in an international market and successful transactions generate a revenue stream for the University that recycles into the Scottish economy. The win-win in the context of what appear to be SE’s main interests is to have: (i) licensing to foreign companies as the catalyst which leads them to locate a business unit in Scotland (with the facilities at Bioquarter as an added attractor); and (ii) for indigenous companies to take-up and benefit directly from the licensing opportunities and the supportive facilities provided on the Bioquarter site.

#### ***Routes to economic impact***

- 3.48 Therefore, in summary, the envisaged routes to economic impact associated with Edinburgh Bioquarter appear to be as follows:

<sup>14</sup> See: <http://www.research-innovation.ed.ac.uk/company/newcompanies.asp>

<sup>15</sup> See: <http://www.research-innovation.ed.ac.uk/licensing/>

- the location and its associated ‘assets’ in the University and NHS (including ‘talented’ people and the opportunities to take-up attractive licensing opportunities) act as attractors to inward investors who establish and sustain business units on site<sup>16</sup>
- the ‘assets’ in the University and the NHS are transferred/commercialised to a greater degree than would have been the case previously as a result of the commercial activity and associated support available on site, and the exploitation of this IP contributes to the growth of new and/or existing businesses in Scotland
  - businesses (inward investors or indigenous firms) locating to Bioquarter develop new or enhanced collaborative ventures with the co-located University and/or NHS ‘assets’ which in turn lead to new opportunities for business growth.

#### *Evidence of impact*

- 3.49 Evidence of the economic development model envisaged for Bioquarter beginning to work can be seen in the recent (May, 2010) announcement that the drug development company TPP Global Development plans to establish a business unit employing c. 15 staff on the Bioquarter site. TPP’s business model is based on licensing IP from universities and research institutes. It raises risk investment capital to develop the IP into “preclinical drug assets” which are in turn sold to large pharma or biotechnology firms, or alternatively spun-out into separate companies.
- 3.50 The routes to knock-on economic benefits to Scotland beyond the direct employment in TPP’s Edinburgh base come, potentially, from: (i) up-front payments and/or royalties due to institutions in the Scottish research-base that license to TPP; (ii) the commissioning of services from CROs or other firms in Scotland as part of TPP’s own developmental process; and (iii) IP licensed from TPP to firms, including spin-outs, based in Scotland which grow as a consequence of successfully exploiting this IP.

#### **Comment on market failure issues**

- 3.51 The rationale for public sector intervention is usually founded either in market failure or where there are clear distributional objectives that need to be met. HM Treasury’s Green Book<sup>17</sup> refers to “where the market has not and cannot of itself be expected to deliver an efficient outcome; the intervention that is contemplated will seek to redress this”. It is also important to assess if it is reasonable to assume that intervention will be cost-effective i.e. that the benefits of intervention will exceed the costs.
- 3.52 Market failure can occur for a number of reasons. Based on our review of the existing TCM-related interventions supported by SE we can envisage the following types of market failure to be relevant in making the case for support:

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<sup>16</sup> During our primary research, informants associated with support for international trade commented on the prospects for inward investment to Scotland associated with TCM. It appears that prospects of attracting companies in diagnostics to Scotland are not highly rated. These consultees reason that the healthcare reimbursement model which operates in the US makes it more attractive as a location for investment.

<sup>17</sup> See: [http://www.hm-treasury.gov.uk/d/green\\_book\\_complete.pdf](http://www.hm-treasury.gov.uk/d/green_book_complete.pdf)



- ‘*externalities*’ – especially in the context of providing enabling support which leads to the conduct of translational research which in turn has ‘spill-overs’ which benefit others not directly involved
- ‘*imperfect information*’ and ‘*asymmetry of information*’ – including on the likely quality and outcomes of collaboration and associated investment in research and innovation. This is relevant both in large scale initiatives such as TMRC and also at the scale of support for individual inventors through SHIL. It is also linked to the uncertainties faced by potential private investors in making an investment in physical infrastructure such as Bioquarter that is dependent *inter alia* on the scale and quality of commercialisation output delivered by the co-located research groups
- ‘*public goods*’ – these are benefits which accrue that cannot be restricted (they are ‘non-rival’ in the sense that benefits for one party does not prevent another party benefiting) or that once made available everyone can take advantage (i.e. they are ‘non-excludable’). Non-excludability can also result in ‘free-riding’ when one party takes advantage without making a contribution to the public good because they expect others will do so. Interventions in support of co-ordination and collaboration – to the ‘soft’ infrastructure in support of innovation - are typically justified on the basis that they are a form of public goods.

3.53 A key feature of the existing interventions has been their focus on addressing what were presumably seen as co-ordination failures to be overcome (or opportunities from enhanced co-ordination to be exploited). The TMRC, NRS Permissions CC, SAHSC and even the coming together of various Health Boards to form SHIL are all associated to a large degree with issues of co-ordination and strategic collaboration between individual (and in some cases diverse) organisations for the good of the Scottish economy.

## Assessing value for money

- 3.54 Given the partnership working and co-funding of the interventions involving different parts of the public sector and universities, the determination of ‘value for money’ (VFM) from the potentially different perspectives of SE and its partners may prove more ‘challenging’ than confirming a market failure rationale for the support. For some interventions it is too early to evaluate this. For others including TMRC and SHIL it is not. This will require the gathering of evaluation evidence directly from the intended beneficiaries (and especially any intended *business* beneficiaries) of each of the interventions (something beyond the scope of the present study). It will require a formal assessment of the net additional impact these initiatives have delivered (to date and still reasonably expected), principally in terms of Gross Added Value to the Scottish economy. This ‘hard’ value assessment can be supplemented (but not substituted) by an assessment of the ‘strategic added value’ investments in the initiatives have generated.
- 3.55 It is conceivable that the basis for assessing VFM used now by some of the organisations involved e.g. SE, may not be the same basis on which the initial impact appraisal was conducted. This will need to be borne in mind by any evaluator of VFM.

## Views of consultees on existing interventions

### ***Business perspectives***

- 3.56 To supplement the above reviews of current interventions, we asked for views from company consultees on their level of awareness of the interventions and on relevance/value to growing their business.
- 3.57 Firstly, most have a general level of awareness that most of the interventions existed but typically not through direct engagement. There were also some notable exceptions, including:
- a CRO not (yet) aware of NRS Permissions CC
  - a substantial number of consultees unaware of the SAHSC
  - a substantial number of consultees unaware of TMRI and SHIL, despite the relative maturity of these interventions.
- 3.58 Of those consultees that did report awareness, we asked for further indication of the nature of the business value of the interventions to date and that expected in future. Given the diversity of views and especially the difficulty consultees had in providing a quantitative assessment of business benefit, we report the responses using the following short narratives:
- “no real benefits can be attributed yet to our SHIL collaboration, but it will be an ongoing process. We are meeting up over the next month to discuss clinical studies to be started over the summer. The early stage of clinical trials makes it unrealistic to identify any benefits over realistic timelines. Without guidance from SHIL, we would have still proceeded unchanged (through another 3<sup>rd</sup> party), but the timelines may have been extended”
  - whilst no benefits from the five named interventions, one firm has had “significant help from SE elsewhere, totaling several million pounds” for training and support for capital infrastructure (refurbishing labs). No direct support from the interventions for R&D. Sustainable impact is sensitive to the future of this firm’s operation in Scotland
  - no benefits from these five initiatives, but the firm has received previous SE financial support as well as funds from the Regional Selective Assistance (RSA) scheme
  - “the TMRC has definitely provided the means of forming a good relationship with Pfizer: also it has opened the door for the company to form a direct collaboration with Pfizer outside of TMRC. Whilst no IP has been generated, it is allowing advances in technology relevant to the firm’s existing markets.” Additionally, as part of TMRC, Wyeth commissioned research/services from this same company to its financial benefit. This relationship also led to the company gaining specific expertise which it is able to sell on (as a service). “TMRC was instrumental in providing these opportunities”
  - none provided to date, but can see future opportunities with: TMRC – “potential for expanding the R&D pipeline by conducting proof of concept studies with TMRI” and with SHIL. Specifically, TMRI is seen as offering a new collaboration and funding opportunity which would be more difficult without its involvement.

- 3.59 The majority of company respondents could not attribute any monetised business value to the five named interventions, although some did acknowledge the importance of other forms of more direct public sector support (from the public sector's 'standard' grants). However, for a minority a business value had been obtained and/or was anticipated in future from engaging with TMRI or SHIL.
- 3.60 We conclude that there is a need for further effort to raise awareness of the nature of these initiatives to TCM-related businesses in Scotland and to re-visit their direct business relevance and over what timeframes.

### ***Perspectives from universities, NHS and other public bodies***

- 3.61 Perhaps unsurprisingly, almost all university, NHS and other public sector consultees were aware of the current portfolio of SE-supported initiatives. We asked for views on the continuing relevance of each to TCM in Scotland, and specifically on their relevance to achieving economic growth objectives – are they addressing the right issues on route(s) to growth? Responses are summarised below, demonstrating the contrasting views that were revealed:
- 3.62 On TMRC, the following comments were made:
- a useful route to establishing better collaboration amongst organisations in Scotland
    - has brought Scottish community together and forced it to work with pharma so positive and remains relevant
  - “a fantastic success”, albeit somewhat diminished over time vs. “should never do it this way again”
    - too complex to function effectively, with concerns over its areas of focus
    - has proved useful, not least in resulting in formation of SAHSC
  - there will be outputs that generate financial returns whilst others express uncertainty over how much IP is there to be exploited
    - “only been running for 5 year”
  - little spillover benefit so far to other firms
    - hoped for wider working with other pharmas
    - a better focus now with Pfizer on ‘grand challenges’: if demonstrated to be successful, it will serve to influence other pharmas and demonstrate an attractive model
    - of continuing relevance, but need to “re-engineer deal” with pharma to ensure solid, sustainable collaboration.
- 3.63 Based on our assessment of this qualitative evidence, there is a polarity of view on the efficacy of the TMRC/TMRI model and its delivery of exploitable outputs. Either because of the model or (just) timing issues, there is limited indication so far of knock-on benefits for the Scottish business base.
- 3.64 On NRS Permissions CC, the following comments were made:

- key to the conduct of trials in Scotland
    - important to get this right as it acts as a one-stop-shop and will be critical to getting permission times down
    - “a gem”, addressing right issues
  - already a “resounding success”
    - providing a simpler mechanism.
- 3.65 Based on our assessment of the qualitative feedback, there is a consensus that the NRS Permissions CC is addressing the right issues and already making a useful contribution.
- 3.66 On SAHSC, the following comments were received:
- “still ambivalent”, whilst for another informant it is “vitally important”
    - also, a “good concept and supportive of it”
  - not yet clear if addressing the right objectives - observed that it was a “good way of getting money out of the NHS locally”
  - “new kid on the block” and seen as very similar to TMRC: need now is to resolve who does what
    - seen as a “successor organisation to TMRC” and considered (in one place at least) as more effective
    - alternative approach to that of TMRC/TMRI – lower cost and still early days to judge. Envisaged as key organisation for ‘research’ but not for clinical trials.
- 3.67 Perhaps not surprisingly given its recent formation, in addition to the highly supportive views received, for a number of consultees the ‘jury is still out’ on SAHSC. Based on our assessment of this qualitative feedback, the SAHSC still has much work to do, even within the research-base, to inform and convince.
- 3.68 On SHIL, the following comments were received:
- although it has not made money to any significant degree, it has added value to the NHS.
  - variously: “OK”; not seen it deliver “anything relevant”; and “not impressed”
  - function is important, but questioning if SHIL is the best model to make it happen: “why not give role to the universities?”
  - recognition that SHIL is in transition, trying to become self- sustaining, but its current stakeholders/customers may not like the proposed model – seen to be “giving away equity for revenue”
  - there were a number of consultees with little or no awareness of SHIL.
- 3.69 We were informed that SHIL is presently re-assessing its business model. This is probably timely given the mixed views we encountered.

3.70 On Bioquarter, the following comments were received:

- endorse the concept: addressing the right issues
- broadly supportive but very early days - too early to assess
- incubation space is needed, but not sure how relevant it is to Scotland e.g. to the needs of businesses starting up in Aberdeen and Dundee, but recognition that it is a good location for development
- for most consultees, only a general awareness so far.

### ***Lessons from the current initiatives***

3.71 ‘Stakeholder’ consultees in the university and public sectors were asked to reflect on any lessons that should be learned from the current portfolio of initiatives supported by SE. The responses were fulsome, albeit only for a sub-set of current interventions: they are summarised in Table 3.6.

**Table 3-6: Lessons from current initiatives supported by SE**

#### **Response/ lessons**

##### **TMRC**

- ensure greater clarity regarding goals; take care not to be too academically focused - focus more on what company wants at an early stage.
- improve appraisals of infrastructure investments (lessons from the TMRC core laboratory – reported as 75% empty and perceived as posing a risk for the host university)
- revisit benefits/dis-benefits of exclusivity in relationship with one company
- getting all HEIs to adopt one set of agreements can be very time consuming and “messy” , but “it has been done” and was a “an important achievement”
- important to have NHS Scotland on board from the outset on similar initiatives in future
- important to develop and shape/structure initiatives with pharma such as this to “get the most out of the academic collaborations”, including better co-ordination with clinical workstreams
- seek partnership of “true equals” with pharma: avoid ‘command and control’

##### **SAHSC:**

- too early for any lessons
- efficacy will be put to the test when a large pharma announces that it wants to locate in Scotland
- importance of focusing on networking and linkages at a strategic level and not only on local level investments

##### **SHIL:**

- better communication needed on activities/achievements
- important to address perception in the NHS that quality of services not been great in all places
- important to acknowledge that this is very difficult area to work in – “capitalising on IP is always challenging”.
- had unrealistic expectations placed on it – “true of many similar initiatives”

##### **Bioquarter:**

- important to continue to give attention/support to making existing developments work rather than overly focus on the building of new ones.
- important to ensure more focus on engaging/leveraging expertise – the intellectual capital

##### **General points:**

- “Scotland is a small country – is the landscape too crowded? – do we need all these initiatives, are things too complicated?”

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**Response/ lessons**

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- need to be realistic about the geography of Scotland – “same population as Greater Manchester. One wouldn’t see the plethora of confusing initiatives there – need to simplify greatly if industry is to be encouraged/supported effectively”
- overall need to be more critical in approach and not create unrealistic expectations
- “people need to behave differently – tribal behavior needs to be put to one side, different mind set needed. Huge potential, but limited time to realise it.”
- need still to enhance partnership working – with industry and senior health consultants who can span boundaries. “Health Boards can make it more difficult to work with industry”
- in general, there is not enough being done to get the message across to academics and NHS Consultants on the opportunities and how they might help to realise them. Initiatives such as TMRC and SAHSC need academics and NHS Consultants to be even more engaged and participating if to be fully effective.

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*Source: SQW’s primary research*

***Points of significance for this study***

- 3.72 From an analysis of all the above, the single key issue we would point to for further action by SE is ensure greater clarity and better communication of objectives and relevance for *all* stakeholders, but especially the relevance of the existing TCM-related interventions for those in Scottish business base.

## 4: Economic and business contributions

- 4.1 We asked consultees in universities and the NHS to identify the types of contribution in the area of TCM their organisations make to *economic growth* in Scotland. Specifically, we also asked how they contribute to the *growth of businesses* in Scotland. The responses are summarised in Table 4-1.

Table 4-1: Institutional contributions to economic and business growth

To economic growth	To business growth
<ul style="list-style-type: none"> <li>direct and indirect employment – including through grant and other income to universities from sources outside Scotland</li> </ul>	<ul style="list-style-type: none"> <li>knowledge transfer/exchange outputs from universities to businesses – albeit elongated times to market make it difficult to track and attribute economic impact.</li> <li>interactions may also help anchor firms in Scotland at a time when many are increasingly mobile.</li> </ul>
<ul style="list-style-type: none"> <li>through contributing to a healthier population - “improved standards of clinical care improve health standards leading to decreased burden on the Health Service and improved productivity etc.”</li> </ul>	<ul style="list-style-type: none"> <li>contribution of IP and support to the creation of new TCM-relevant companies – but not always attributable to an institutional focus on TCM.</li> </ul>
	<ul style="list-style-type: none"> <li>Commissioning work from companies in Scotland.</li> </ul>

- 4.2 It is notable, and in our view understandable, that the informants pointed *inter alia* to contributions from TCM to the economy through contributions over time to a healthier population. The partners involved in the current set of TCM-related interventions are likely to have different, albeit overlapping, missions and incentives.
- 4.3 In this regard it is interesting that Suhrcke<sup>18</sup>, Professor of Public Health at the University of East Anglia, recently reported that:

*“Despite increasing recognition of the link between health and economic development in low-income countries, the relationship has to date received scant attention in rich countries. We argue that this lack of attention is not justifiable. While the economic argument for investing in health in rich countries may differ in detail from that in low-income countries, there is considerable and convincing evidence that significant economic benefits can be achieved by improving health not only in poor, but also in rich countries. Better health increases labour supply and productivity and historically, health has been a major contributor to economic growth. In spite of remaining evidence gaps, economic policy-makers also in developed countries should consider investing in health as one (of few) ways by which to achieve their economic objectives.”*

- 4.4 Although ‘productivity’ is relevant, of course, to SE’s economic development objectives, the link between population health and economic benefit is not one that as far as we know SE has considered to date. The ‘theory of change’ here is complex, with beneficial change likely to be over extended timeframes. Making the link in Scotland at this time is more important for the funders of translational research and the recipients of these funds than it is directly or solely for SE.

<sup>18</sup> Suhrcke, *et al* (2006) The contribution of health to the economy in the European Union. *Public Health* vol. 120 (11)



- 4.5 A number of consultees noted that often they find it difficult to track and attribute contributions explicitly to outcomes or impact relevant to economic and business development. Indeed, one argued that: “a lot of ‘hot air’ is spoken about economic contributions”, suggesting that: “when connections between TCM and economic impact are visible, this has been serendipitous not systemic”.
- 4.6 One consultee cautioned against viewing TCM as a “driver of economic growth” over the next 5 years although its contribution could be important over the next 10 years, a timeframe beyond SE’s own current business plan.
- 4.7 We sense that there remains a task for SE to articulate more clearly for its partners the economic development needs and aspirations associated with the portfolio of interventions in support of TCM, especially those involving academic and NHS collaborative activities.

## Key business issues

- 4.8 From ten businesses consulted during the study, we list below the main business development issues to emerge. Not surprisingly perhaps, the issues vary depending on the nature of the company. The sample size does not permit analysis and generalisation so we have chosen to link the type of company with the comment made:
- *for a biotech company with a project at the clinical stage* – the prime requirement is a link to pharma as potential first commercial customer
  - *for a global provider of research models and preclinical, clinical and support services which span the entire drug development process* – the firm operates on a global scale, with very little direct contact at present with Scotland’s TCM arena: perhaps because of this, the view is that few factors in Scotland are likely to affect the company
  - *for a company with its own R&D team to exploit university and its own IP* – the key requirements are access to continued investment; access to a pool of skilled people; and suitable premises
  - *for a wholly pre-clinical operation of a global pharma* – the most important business issues are: access to a good university network (world-class research in relevant areas; high calibre graduates across relevant disciplines); access to the NHS and to patient records. A negative factor in Scotland is described as the costs of the “core infrastructure” compared to elsewhere
    - this informant refers to facing competition in pre-clinical R&D not only from commercial firms but now also from academic research groups.
    - pharma sector undergoing significant change - consolidation and outsourcing to Singapore, China and India, both for R&D and more so clinical trials. These are strategic markets and cheaper to operate in than Europe
  - *for a supplier of services to pharmas for drug safety (e.g. pre-clinical stages of toxicology and drug metabolism) and in-house drug development* –this informant pointed to the following positive features: at UK level, favourable fiscal environment and incentives (such as R&D tax credits); in Scotland, importance of the profile given

to Life Sciences as a priority sector by the public sector; also access to clinical excellence (e.g. at Beatson Institute, Glasgow)

- *for a company with manufacturing, R&D and diagnostic product development in Scotland* – the firm’s future growth is reliant on “global dynamics”. The company is tapping into business opportunities in emerging international markets through its overseas operations in these countries
- *for a university spin-out with a drug product pipeline focused on ‘orphan diseases’ (i.e. niche markets)* – it not so much factors within Scotland that will affect this company but international ones, especially its ability to penetrate the US market and then enter Europe
- *for a provider of services, e.g. on regulatory compliance; supporting drug discovery; analytical and drug testing* – its market is the pharma and biotechnology sectors predominantly in the UK, with no significant market in Scotland. It operates in a “fiercely competitive” market with CROs, CMOs and analytical companies
- *for a diagnostic company, using licensed-in IP for worldwide use* – it values the support from NHS and universities in Scotland
- *for a company that screens drugs for pharma companies, having a CRO and R&D function in Scotland* – its future growth is reliant on expanding its sales pipeline, including through sales in the USA.

4.9 Based on this feedback, what we judge to be notable is the importance of the global rather than the domestic business environment and of access to international markets for the majority of the firms. This emphasises the importance of the work of Scottish Development International and others in supporting export.

### ***Benefits to businesses from universities and the NHS in Scotland***

4.10 We also asked business consultees if their company benefited currently from universities or the NHS in Scotland (i.e. not just restricted to those SE-supported initiatives reviewed elsewhere in this report) - as collaborators, customers or in other ways. The responses are summarised below again in a manner that allows the reader to see the diversity of responses:

- little or no engagement (3 respondents)
  - with one consultee noting collaboration with universities outside Scotland
  - one with the prospect of collaboration with universities via TMRI over proof of concept work
- yes, with universities (7), including:
  - access to academic expertise; via funding post-graduate projects and post-doctoral placements
  - access to research services, consultancy advice and academic expertise, and sponsorship of CASE Studentship - all in pre-clinical areas
  - involvement in a Knowledge Transfer Partnership (KTP) project

- yes, but only over graduate recruitment
  - yes, with the NHS (5), including:
    - access to models and materials
    - NHS as a customer and involved in collaborative clinical studies.
- 4.11 Companies more commonly referred to specific activities involving universities than the NHS, although even here the picture was mixed. Many of the benefits referred to appear to be associated with pre-clinical activities.
- 4.12 Following on from this query, we asked specifically about the nature and scale of business opportunities and benefits anticipated in future arising from: (a) R&D conducted by Scotland's universities and the NHS; (b) access to knowledge/expertise in Scotland's universities; and (c) access to patients/patient records in Scotland. This to some degree helped to tease out the extent to which the strengths in the TCM 'landscape' in Scotland are of direct value to businesses.
- 4.13 Consultees who gave positive responses were generally unable to quantify the business benefits: they referred to the ease of conducting high quality collaborative studies in Scotland, albeit those with substantial in-house R&D envisaged marginal benefit from such opportunities. For subsidiaries of large international companies, they will go where the relevant centres of excellence exist, in Scotland or anywhere globally – and either for commissioning R&D or access to knowledge/expertise.
- 4.14 For an SME engaging in clinical trials, there would be great attraction in collaborating (joint venturing) to share cost and risk, and simply to get more potential products assessed.
- 4.15 For one consultee, access to patient records (and to patients) is likely to bring opportunities associated largely with early phase trials (e.g. proof of concept studies) and involving low patient numbers. The implication of other responses seems to be that perceived population size constraints for trials in Scotland may need to be re-assessed in light of shifts towards stratified and ultimately personalised medicine, including through the greater use of biomarkers.

#### *Impact on R&D spend*

- 4.16 We wanted to determine if collaboration with universities and/or the NHS in Scotland had resulted in companies increasing their own funding for R&D in support of innovation objectives.
- 4.17 For one company, the opportunities afforded by the KTP scheme had encouraged R&D spend. Two other company respondents highlighted the mixed sources of incentives and resources for R&D. For one, there has been a consistent company policy of ring-fencing c. 30% of its R&D budget for external projects, but these could be commissioned in Scotland or globally: this indicates a strong acknowledgement of the business value of external collaboration. Although the company's budget is of course "finite", as much of its R&D is collaborative there are opportunities to leverage in more R&D funding, including from their external (pharma) partners.
- 4.18 For the second company expressing strong business support for R&D, including extra-mural projects, negative experiences in Scotland mean that university collaborations now take place with institutions elsewhere. (This points up the fragility of the 'brand'.) Funding for this firm

has come from its own resources, from venture capital investments and from public sector grants (e.g. SMART).

- 4.19 There is no strong sense that opportunities to collaborate with university or NHS researchers in Scotland are directly linked to firms increasing their support for R&D. Rather, those that are committed to R&D make decisions over how to spend their available R&D budget, leveraging resource from public sector grants or supply chain collaborators, and for extra-mural R&D selecting university collaborators from a broad, international pool on case-by-case criteria.

*Business impact of R&D associated with clinical trials*

- 4.20 More specifically, we asked company contacts if they achieved increases in sales revenue or created/safeguarded high value jobs as a result of undertaking contract R&D associated with clinical trials and involving Scottish universities and/or the NHS. The diverse nature of the companies selected for interview probably contributed to mixed results:

- not applicable (5 companies) – reasons include: no R&D undertaken; no NHS/university collaboration; at pre-revenue stage; pre-clinical focus
- revenue now coming from products that were subject of earlier trials (1 company)
- no increase in sales revenues. As for jobs, it is more important for the firm to have the right skilled jobs (i.e. scientists) than the numbers employed. Largely export driven (1)
- business benefits from university links but not with Scottish universities (1).

*Benefits of licensing IP*

- 4.21 We also probed for business benefits arising from the introduction of new products or services that are based on IP acquired from universities or the NHS in Scotland. Not surprisingly perhaps given the mix of companies interviewed, the responses were polarised:

- not applicable so far – at pre-revenue stage and employment unaffected (1 company)
- not applicable – pre-clinical (1)
- no/not applicable (3)
- company was established to exploit university IP under license (1)
- yes, company does license-in university IP and is beginning to increase revenues from first product launch (1)
- staff numbers increasing in Scotland, but not attributable to collaboration with research-base in Scotland (1)
- yes – this drugs screening business benefits from licensing from universities and constantly scans for new IP opportunities. Building on this, its intra-mural R&D is expected to yield bottom-line benefits through increased sales after a c. 6 month development period (1).

- 4.22 These responses point up the importance of SE and its partners understanding the segmentation of the TCM-related business base and the way in which different parts at different phases of their development may view the output from the existing interventions to be of relevance/value.

*Identifying future opportunities*

- 4.23 In the context of the TCM landscape in Scotland, we asked company consultees to identify any other business opportunities they saw arising. Given SE's current objectives that focus on business benefit, the following findings are especially important. The responses were 'optimistic', albeit diverse:

- *clinical trials*: opportunities arising in clinical trials, but need to develop enhanced relationships with key players in Scotland
- *animal trials and sharing best practice*: current work relating to animal testing is allowing best practices to be shared between the company and a Scottish university
- *graduate education*: opportunity to collaborate with universities to address a gap in graduates' understanding of the heavily regulated requirements of the pharma/ clinical sector (GLP/GCP etc) - opportunity to better educate students to enter the field of TCM
- *opportunity for more contract work on behalf of universities*: seen as a growth area now that universities are undertaking more early-stage drug discovery research (e.g. with Wellcome Trust funding). One company reported that it is already testing compounds for university customers, but also sees future opportunities for collaboration over drug discovery
- *consultees uncertain about the future*: one company may diversify into diagnostics; the future of another company's present site is unsure.

- 4.24 To address a specific requirement of the client, we asked company consultees to estimate the likely significance of all the opportunities that they can identify, giving an indication of the likely scale of impact on turnover and employment in absolute or percentage terms. The responses point up the challenge facing SE in assessing *ex ante* the likely impact of its interventions in support of TCM:

- cannot quantify ( 2 companies); too early (1 company)
- none or not applicable (3 companies)
- "quantifying by turnover is not relevant as work is pre-clinical"
- ensuring present site remains open would safeguard c. 300 jobs
- income from drug discovery IP to double in the next 3 years
- collectively, opportunities will lead one firm to double its workforce from 9 to 18 staff, with two thirds of them being lab-based, over the next 18 months.

- 4.25 From our analysis and interpretation, the key business issues raised by company consultees in terms of realising future opportunities include:

- *external markets*: importance of entering wider UK and European markets

- also securing recently identified prospects in the US market
- *resource constraints*: overcoming immediate barriers associated primarily with availability of human and financial resources - staff requirements plus cash injections to be addressed over the next 6-12 months
- *creating ideas and access to IP*: remain open to new ideas and look to access suitable IP, from Scotland but also looking to Europe (e.g. France)
- *barriers to university collaboration*: find ways to address barriers associated with time, administration and funding when seeking collaboration with universities: “The private sector works much faster than the universities and government so this can cause costly delays”. “Universal” material transfer agreements with universities are a useful step forward.

## Growth prospects for pre-clinical studies and clinical trials

- 4.26 The market for translational research appears to segment into two, albeit with a ‘grey area’ in between:
- industry-sponsored clinical trials – referred to by some consultees as ‘standard’ trials
  - science added-value trials, including pre-clinical studies.
- 4.27 The sponsors of the former may wish to engage experienced NHS Consultants and/or General Practitioners in the trials. The latter types of trials involve research-active staff in universities and/or the NHS because of the ‘intellectual’ content and challenge. On commercial trials, NHS Consultants are perceived to be motivated by the prospect of early access to new/better treatments for their patients. Commercial work also brings them income which they can re-invest in their clinical research facilities.
- 4.28 There are divergent views on the nature of constraints on the scale of trial activity in Scotland. Some consultees have pointed to constraints based on the capacity of academic and NHS staff, including researchers and/or research-trained nurses. Facilities such as access to x-ray equipment may be identified as a constraint, but access to this type of service could be purchased from the private sector if needed. Other, similarly authoritative consultees dismiss this argument, claiming that NHS capacity issues do not constitute a constraint at present. However, even one consultee who held the former (constrained) view asserted that “Scotland could cope with another Wyeth”.
- 4.29 Incentives for clinical academic staff are seen as a key element in increasing the volume of trials. According to one consultee: engagement in clinical trials is not seen as delivering major career benefits to staff but it is still motivated by a concern for patients. In taking forward growth objectives for clinical trials, one consultee advises SE to “get a better understanding of the inner workings of the NHS”.
- 4.30 Commercial involvement in TCM can take a number of forms, as already evident in Scotland: R&D and trials funded by pharma companies on a contract-by-contract basis; collaborative research as part of a strategic partnership as in the present company-supported TMRC/TMRI

initiative. (The collaborative research conducted within the TMRC has as an output the requirement for Phase 1 clinical trials.)

4.31 We wished to understand the route to business benefit here for CROs, given the emphasis placed on this part of the ‘supply network’ in Scotland. A number of relationships are relevant:

- large CRO with a strategic partnership with Health Boards, with CRO staff ‘embedded’ in Board premises
- CRO submits a bid to pharma to undertake a trial and upon winning the work engages with the NHS over design and implementation
- pharma approaches NHS and upon agreement the pharma then looks to engages a CRO – our consultee indicates this route “never happens”
  - however, in the above cases there may be “tripartite” arrangements in place where pharma contracts with the NHS and the CRO supports the trial. ‘Generic’ tripartite arrangements have been developed with the aim of streamlining the contacting processes
- pharma wishing to undertake trial approaches NHS with no intermediary (contractor) involved at this stage.

4.32 In essence, the business process is that the pharma company usually selects the CRO itself based on the service/product offer. The CRO seems to operate in responsive mode to market opportunities, albeit benefiting from a track record of successful assignment experience with the commissioning pharma company.

4.33 The crucial role of the pharma company is evident here as is its relationship with the NHS: business growth for CROs would appear to be highly dependent on this axis of engagement. For pharma, we were alerted to four key business conditions: (i) cost of the trials; (ii) the efficiency of the approvals process; (iii) ability to recruit patients; and (iv) ability to deliver to quality and time. The role of the NRS Permissions CC in ‘sensing and responding’ to these market factors is highly relevant. As well as helping to address these factors when responding to approaches from pharma companies, continued effort in pro-active marketing – selling Scotland internationally to pharma – will also be important.

4.34 We have obtained recent information collated by NHS R&D Directors on the extent of CRO involvement in pharma trials in Scotland. Of the last 32 projects which have gone through the NRS Permissions CC’s multicentre approval process, only 12 used CROs. Of those, 5 were Quintiles studies. In the other seven pharma trials with CRO involvement, the CROs engaged were: PRA International, Parexel, Icon, CDS Medical Research, Kendle UK and PPD. This list includes CROs which do not have a Scottish base.

4.35 We were advised by one consultee that, based on the majority view of NHS R&D Directors, there was little more to be done to boost domestic CRO activity, and that this was not an area in which Scotland could expect to see any significant expansion.

4.36 We also encountered quite divergent views on the positioning of diagnostics companies within the TCM ‘system’ in Scotland: ‘diagnostics companies are more stand-alone (than CROs) in terms of their position in TCM ’ and ‘there are strong links between TCM and diagnostics – within growth in TCM there will be a parallel growth in diagnostics’.



## 5: Scotland's competitive positioning

5.1 Scottish Development International (SDI)<sup>19</sup> promotes Scotland as a place to invest in translational medicine for the following reasons:

- the presence of leading international researchers
- access to translational and clinical science expertise
- a centralised healthcare system
- the presence of collaboration opportunities, and
- state of the art research facilities.

5.2 It also reports in its promotional material that:

*“In harnessing the collaborative abilities of world-class research and clinical expertise, Scotland has emerged as a global leader in the field of translational medicine. The country has a proven ability to deliver large and complex collaborative translational projects<sup>20</sup> that meet research, clinical and commercial objectives in multiple key diseases.”*

and that:

*“Scotland is the partner that can offer faster<sup>21</sup> and more effective progress from ‘bench to bedside’”.*

### World standing of Scotland as a clinical research lab – company view

5.3 We sought to test the claim made in the national strategy for the Life Sciences that Scotland should aim to be the best clinical research laboratory in the world. We asked consultees how close Scotland was to this position. We also asked how success towards this aspirational claim might be judged and tracked. The responses are largely positive, but with caveats. As we see no value in overly distilling down company responses, the views of respondent are summarised in Table 5.1.

Table 5.1: How close is Scotland to being the best clinical research laboratory in the world?

Assessment	Company responses
Close	<p>Scotland is 65-70% of the way there, but the biggest issue will become cost. India, Singapore and Eastern Europe are all emerging as being cost effective and will prove a big issue when the big pharmas are confident with the ethics and approvals processes in these countries. This will be another lost opportunity for Scotland.</p> <p>Scotland is highly regarded and recognised as a location for TCM. It is distinct from England and the rest of the UK.</p>
Close in part	<p>Scotland has a strong biological understanding, with groups willing to take on any research projects. In oncology, Scotland has a high level of understanding in TCM but, according to</p>

<sup>19</sup> See: <http://www.sdi.co.uk/Key%20Industries/Life%20Sciences/Sectors/Translational%20Medicine.aspx>

<sup>20</sup> Presumably referring to TMRC.

<sup>21</sup> It is notable that again the *time* to benefit is highlighted, raising, we would argue, an expectation of ‘time additionality’ being a factor in SE’s TCM-related interventions.

Assessment	Company responses
	<p>this consultee, predominantly in the theory, with only a few pockets of excellence in translating to commercial products.</p> <p>There are key capability elements in research areas such as bio-modelling and mutation analysis.</p> <p>However, within oncology, the consultee argues that "Scotland is struggling to keep its head above water". The reason being that in Scotland patients are presented late, and in a more advanced state. Therefore the patients are in a worse condition to test drug efficacy – and potentially less likely to respond than with an earlier presentation of the disease. "These are 'unfavourable' patients to have on a clinical trial where the aim is for the drug to succeed".</p> <p>Scotland also suffers from a lack of integration across the country. The key elements are present, such as for predictive medicines. In the US this is a major area of importance for big pharma which are undertaking predictive research with the Health Institutes because the former are struggling with their discovery pipelines. "In the UK, we need to get the big pharma (AZ, Pfizer etc) on board, otherwise this opportunity will pass us by".</p>
	<p>In relation to the quality of clinical research, Scotland's status is very high but lags in other areas, notably in relation to regulatory issues.</p>
	<p>Scotland is already a world-leader in TCM in women's healthcare, and in other areas, notably cardiovascular.</p>
	<p>This is a very ambitious statement – it depends on what areas are being targeted, for example historic strengths have been in cardio-vascular, whilst future opportunities lie in diabetes and Alzheimers for example.</p> <p>The patient identifiers (records) and a stable population make Scotland unique, which does make for a differentiation from England and the rest of the UK.</p>
<b>Not close</b>	<p>Scotland could become a world leader, but: "with its present (risk averse) leadership it is heading for disaster. Ambition, strength, vision and leadership are needed, but are not in place. Scotland is only 10-15% of the way towards being the best clinical lab in the world, compared to such examples as Harvard, Duke. San Diego and Stanford are other examples."</p>
	<p>Scotland has certainly embraced this vision and has made progress, but much more needs to be done: enhanced communication between different actors; speeding up of process from ideas to trials, including approvals (although recent progress is acknowledged).</p> <p>This consultee argued that success can only be tracked by external metrics relating to the Nation's health, i.e. to see a downward trend in key areas – cardiovascular, cancer and obesity.</p>
	<p>Scotland has come a long way in bringing TCM together, but it is not operating at an international level.</p> <p>Progress could be tracked either through disease levels or through use of diagnostics.</p>
	<p>Scotland would not even register on the global scale. It has the potential to be recognized given its existing strengths but with a Scottish population of 5m and a UK population of &gt;60m it may not be able to differentiate itself from the wider UK.</p>

Source: SQW's primary research

- 5.4 It is notable that almost no one dismissed out of hand the appropriateness of the ambition: some queried feasibility and others the status of current position relative to peer areas. Some pointed to niches where world class excellence already exists in Scotland, but issues associated with nearer to market translational activity were raised as falling short of world class.

## World standing – other assessments

- 5.5 The responses from consultees in universities, the NHS and other public bodies on the standing of Scotland as a clinical research laboratory are summarised in Table 5.2.

Table 5.2: How close is Scotland to being the best clinical research laboratory in the world?

Assessment	University, NHS and other public sector responses
<b>Close in part</b>	<p>Scotland is already there if judged on quality and impact of publications per head of population. Consultee also refers to previous track record e.g. statin trials and inventions of beta blockers, insulin pens, MRI.</p> <p>However, historically Scotland has failed to capitalise on the potential economic returns from such activities.</p> <p>How judged? - Will be judged against competitors/other potential collaborators by big pharma e.g. against capability/capacity in China.</p> <p>Aspiration valid and many of the key components already in place.</p> <p>How judged? - By big pharma (important for economic growth), but also by research funding organisations, e.g. MRC, Wellcome Trust and big charities.</p> <p>Scotland has an edge due to good education and research, and supporting infrastructure is good. Less certain about capacity/ capability to attract inward investment.</p> <p>How judged? – in four domains: knowledge, science, healthcare and wealth.</p>
<b>Not close</b>	<p>A lot would have to happen for Scotland to be viewed as the best clinical research lab in the world. This consultee is not even not sure that Scotland is viewed as one single entity with respect of TCM.</p> <p>Although TMRC for example has “had a good press”, there are doubts around what it has actually achieved so far.</p> <p>Some way to go whilst acknowledging the assets of a stable population, a scale which permits significant studies to be conducted; high quality academics and healthcare of high standard. With these assets Scotland should be capable of attracting further investment.</p> <p>How judged? – research outputs, grant income.</p>
<b>Reasonable aspiration</b>	<p>Reasonable aspiration and Scotland is well placed already to achieve this.</p> <p>How judged? - by Directors of World Research in pharma companies and Venture Capitalists.</p>
<b>Reasonable aspiration – could be close in c. 5 years</b>	<p>Reasonable aspiration to Scotland is well position given the following existing assets: well integrated TCM system; good reputation amongst big pharmas; world class laboratories and Imaging expertise/facilities; stability of health care system and population; very good tissue banking and record keeping; individuals with good vision; indications that key people in the USA consider Scotland to be well positioned. .</p> <p>More difficult to judge ‘how close’ Scotland is to this aspiration: “probably not at the top but could get close to the top in the next five years”.</p> <p>How judged? - evidence of high standing from research grants from big charities such as Cancer Research UK; ability to continue to attract high (often world) class clinical academics and clinicians. Also judged by large pharmas and investors - companies such as Alexandria Real Estate (<a href="http://www.labspace.com/site.asp">http://www.labspace.com/site.asp</a>) which came to Edinburgh to invest in Bioquarter “as they couldn’t find anywhere similar in Europe”.</p>
<b>Valid aspiration</b>	<p>Aspiration is valid: Scotland has high quality, easily navigable health service – small number of people and Health Boards so easy to deal with: excellence in its scientific and medical talent; a holistic healthcare system in the NHS – coherent, organised well across the care pathways; good data (but ‘perhaps’ poor IT systems) - medical records very coherent; devolved government means close alignment with political levers/influence.</p> <p>How judged? – by politicians. “When TCM is viewed as offering same scale of opportunity as Alternative Energy, then we will know we have ‘got there’.”</p> <p>Valid aspiration. The important assets to have are: speed of response; centralised and minimalised bureaucracy; ability to deliver and at low cost. Scotland can do first three of these, others can do them more cheaply e.g. China, but at moment the other strengths are more important.</p> <p>How judged? - – big pharma will judge on the on the criteria above.</p>

Source: SQW’s primary research

5.6 Interestingly, the views in Table 5.2 are more mixed. Although the aspiration is widely if not wholly accepted as valid, there is a strong sense of a need for a better evidence base upon which to judge and track Scotland’s status. However, from the cautionary views of some

informants on growth prospects for trials activity in Scotland (see Section 5), having the ‘best lab’ may not necessarily translate directly into the growth of trials activity, and perhaps especially not in terms of growth in industry-sponsored multi-centre trials.

## Competitors

- 5.7 Consultees were asked to name any national/international competitors in TCM and to indicate the nature of this competition. They were asked to recommend ways in which Scotland’s position relative to these areas could be validated. The responses are given in Table 5.3.

Table 5.3: List of Scotland’s competitors in TCM

Institution/area	Comment
UK: Oxford, Cambridge, London, Manchester	Our view is that there has been significant public-sector intervention and substantial activity to enhance collaboration between centres of excellence in universities and the NHS in parts of England over the past few years. Given the reference in the Life Sciences strategy to Scotland to the importance of critical mass, these activities are highly significant in terms of Scotland’s competition for translational research funding.
International: USA (Boston, New York, Seattle, San Diego, San Francisco), China, India, Sweden, Singapore and to lesser extent pockets in Australia, Germany and France	For USA, especially for early stage trials.  But according to one consultee, Scotland does not have many direct competitors: “not convinced about Singapore - no clinical science; “China - not yet trusted”; North America – “doesn’t have medical records”; Sweden – “Karolinska Institute doesn’t have a hospital”.
Mayo Clinic	See: <a href="http://www.mayoclinic.com/health/aboutthissite/aboutmayoclinic">www.mayoclinic.com/health/aboutthissite/aboutmayoclinic</a>
Massachusetts General	See: <a href="http://www.mgh.harvard.edu/about/default.aspx">www.mgh.harvard.edu/about/default.aspx</a>
Karolinska Institute, Sweden	See profile in Annex.

Source: SQW’s primary research

- 5.8 The approaches proposed by non-business consultees to validate Scotland’s position relative to these competitors focused on research-related metrics, e.g. publications, citations, research income, patents – and not knowledge exchange or commercialisation metrics.

## Strengths and weaknesses of the TCM landscape

- 5.9 Consultees pointed to a number of strengths and weaknesses of TCM in Scotland relative to UK and international competitors.
- 5.10 Company consultees were asked firstly to rate their knowledge/awareness of Scotland’s R&D capabilities in TCM in universities, the NHS and in companies. The responses on level of awareness of the R&D landscape in TCM paint a mixed picture: the level of awareness of the role of the NHS is generally low amongst this sample of firms.
- 5.11 Table 5.4 collates responses from company consultees on strengths and weaknesses of the landscape in Scotland for TCM.

Table 5.4: Perceived strengths and weaknesses of the TCM landscape in Scotland – company responses

Response	Number of companies
<b>STRENGTHS:</b>	

Response	Number of companies
<i>A relatively sick population</i> - access to sick people (patients)	5
<i>Access to good patient records</i> – “perhaps best in world”	3
<i>Linkages</i> : good links between academia, NHS and CROs. Progress made in getting different organisations to come together in TCM – notably NHS and universities	3
<i>Quality of clinical research</i> – Beatson Institute in Glasgow singled out by one respondent	3
<i>Small geography size</i> is an advantage – aids a joined-up approach; relatively easy to get key parties together; good networks including those led by university research groups	2
<i>Volume and quality of biomedical research</i> generally – largely, according to one consultee, in universities	2
<i>Pricing</i> - more realistic than elsewhere in the UK for clinical trials.	1
<i>Strong educational base</i>	1
<i>Presence of MRC and Cancer Research UK in Scotland</i>	1
<i>Access to biobanks</i>	1
<i>Tax</i> : at a UK level, the favourable fiscal environment and incentives (such as R&D tax credits)	1
<i>SE support</i> : the focus of SE on putting Life Sciences as a priority sector	1
<i>History/tradition</i> in medical research and education	1
<b>WEAKNESSES:</b>	
<i>Ability to commercialise R&amp;D</i> : - needs better collaboration between universities, the NHS and SMEs. Poor at transforming R&D to manufacturing – one consultee argued that Scotland should not seek to compete here but rather focus on intellectual capital and exploiting IP.	3
<i>Access to finance</i> in range £10-20m – funding at the £1-4m level is available. According to a second consultee, whilst there is strong (early stage) Angel market, there is a lack of later stage venture capital.	2
<i>Approvals</i> : relatively slow speed of regulatory approvals – 14 days in The Netherlands	2
<i>Geographic size</i> is also a disadvantage – cap on capabilities, including to attract new firms, and limitation for trials of size of population As described by one consultee, patient numbers are a restriction, especially for the niche market drugs where there simply are not enough patients/ and or volunteers. It can be done for early phase (low patient numbers) but at phase 3 which requires some 3-5,000 patients it becomes difficult.	2
<i>Selling</i> : insufficient ‘selling’ of Scotland to attract more clinical studies and FDI	1
<i>Capability</i> : absence of “centres of discovery” – such as those found in other TCM ‘hotspots’ such as Boston, San Diego, Seattle, Oxford and Cambridge	1
<i>Risk aversion and leadership</i> : senior personnel in R&D within the NHS and universities of Scotland generally risk averse and poor leadership in commercial environments.	1
<i>Price</i> : scale of overheads charged by universities and NHS for services: one consultee quotes as an example Cambridge charging 107% of costs, whilst Aberdeen charges 114%.	1
<i>Absence of any large company champions</i> in Scotland – “there have been glimpses of this happening with PPL Therapeutics, but Scotland seems to fail in delivery on large scale”.	1

Source: SQW's primary research

- 5.12 One company consultee argued that although Scotland has many of the “pieces of the jigsaw” in TCM, there was still a need to enhance how they worked together. However, by contrast, another noted that its collective strengths have already made Scotland attractive for clinical trials, especially in key therapeutic areas such as cardiology, oncology and extending to areas such as Multiple Sclerosis.
- 5.13 Also in the context of identifying strengths and weaknesses, one consultee engaged in R&D/discovery indicated that on access to tissues banks for its work on oncology, it would generally go outside Scotland, if not outside the UK.
- 5.14 Although consultees raised a fairly diverse range of issues here, recurring references are to strengths associated with availability of a relatively sick population with good patient records plus the quality of the research base: recurring references to weaknesses are associated with commercialisation and with access to venture capital. (The latter is a potentially crucial barrier to company growth if indeed the scale and quality of ‘demand’ for capital is significantly outstripping accessible supply. More than this evidence is required to confirm this but other recent views add strength to the contention.<sup>22</sup> The scale of Scotland is seen variously as an advantage and a constraint.

## Other views

- 5.15 The strengths and weaknesses of the TCM landscape in Scotland according to consultees from universities, the NHS and other public bodies are summarised in Table 5.5.

Table 5.5: Summary of Scotland’s strengths and weaknesses in TCM – stakeholder views

### STRENGTHS:

**Research capability:** basic and clinical – ability to attract research and clinical ‘talent’

**Medical Schools:** scale, tradition and continuing excellence/esteem.

**Subject-specific strengths** in: diabetes, metabolic medicine, stem cells; epidemiology

“cancer should be better – clinical collaboration on cancer research is poor”

only in sub-specialisms of neuroscience

**Medical records** - unique identifiers for patients makes them easy to track

**Ability to collaborate** – including between Health Boards and between universities through SAHSC, the latter reducing competitive pressures

**Responsiveness** – ability for fast delivery

<sup>22</sup> In a lecture at Imperial College, London in April this year on the commercialisation of medical science, Professor Sir Christopher Evans a leading medical science entrepreneur with a track record of establishing successful science companies and founder of the VC firm Merlin Biosciences argued that:

*“The pace of medical discovery and innovation, especially with the increasing power and input of computer technology, has led to a phenomenal build up of excellent IP in universities and institutes and in many small companies. There has been no finance, nor the environment, to nurture credible spin outs and so this IP has stockpiled for the last five years and will continue to accumulate for the next three years. In amongst these huge scientific warehouses are many hidden gems, projects with the potential to make an explosive impact in the financial markets when they are receptive again. Commercialisation of medical science will never cease. It has been temporarily stymied over the last five years but the next five years could see the launch of some of the most exciting medical businesses for decades.”*

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**STRENGTHS:**

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**Support from SE**

**Stable population for trials**

**Population with relatively poor health**

**'Simple' health system** – relative to England

**Good clinical and imaging facilities**

**Quality of education and training** – excellence of medical schools

**Single access point for trials Permissions**

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**WEAKNESSES:**

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**Application:** ability to transform research to practical application. R&D to commercialisation interface remains "problematic"

**Subject specific weaknesses:** one consultee pointed to ophthalmology<sup>23</sup>

**Trials:** too expensive, too slow and suffer from under-recruitment.

**Engagement of NHS consultants:** level of engagement of NHS Consultants in trials not optimal – needs to be enhanced – a constraint

**Low profile** – including invisible to many investors e.g. VCs based in London

**Lack of vision** regarding the development of the enabling physical infrastructure – one consultee contrasted poor transport links to Bioquarter with the Bay Area of San Francisco where the authorities have invested in a Light Railway. (It was noted that the Little France area -associated with Bioquarter -has the same population as Perth.)

**NHS operations:** although senior level executives in the Health Boards are supportive, blockages are encountered at middle management level

**Partnership working** – partnering of HEIs needs to be made stronger – a constraint

**Size** – a small market in world terms – constraint

**HEI incentive structure** – "gets to a certain point where institutional interest over-rides any collaborative desires".

**Academic career structures and rewards** - "barriers placed in way of researchers who have history of working with industry (e.g. on Advisory Boards) but who are increasingly discouraged in this by employers (both NHS and HEIs) – doing now despite not because of their employers.

Failure to see these individuals as Medical Ambassadors." This consultee drew contrast with esteem gained by South Korean professors because of their links with industry.

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*Source: SQW's primary research*

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- 5.16 We would argue that the key issues here are the perceived weaknesses associated with industry engagement and commercialisation.

## Testing strategic propositions

- 5.17 With the agreement of the client, we tested with all primary research contacts the validity and opportunities associated with four propositions that we culled from statements made in SE's own documents addressing the development of TCM in Scotland. This complements the responses of consultees to our more 'open' research questions that elicited the views expressed in the earlier parts of this section on competitive positioning.

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<sup>23</sup> This may link to a wider issue for this discipline in the UK which is beyond the scope of this work to consider further. See: Sparrow (2006) British academic ophthalmology in crisis. *British Journal of Ophthalmology* 90 (4)



- 5.18 Firstly, we summarise the company responses to each proposition. We record individual responses before offering our analysis and conclusions based on what are sometimes quite diverse views.

## Companies' assessment of the propositions

- 5.19 Each company's assessment is set out in a single row of the charts below. Three out of the four propositions presented as stated in SE documentation give prominence to CROs. This accounts for the emphasis placed on these companies in the responses rather than any additional direction provided by SQW's consultants.

**Proposition 1:** the growth opportunities from TCM for businesses in Scotland (existing, new and/or inward investors) are likely to be associated with the growth of Contract Research Organisations and diagnostic companies. Is this likely to be valid? Any other opportunities?

Assessment	Company comment
Not valid	"No sense of growth apart from Quintiles". No sense of move to enhanced collaborations. Suspects that the industry may not know much of what the NHS is doing.
Not valid	Consultee agrees that TCM will grow in Scotland, but that this will be driven by the NHS and the universities, not the CROs. CROs and diagnostic companies will grow on basis of demand, rather than lead.
Not valid	CROs are global and are governed by costs, globally. Without any other interventions, CROs will just continue at current growth rates. Likewise, for diagnostics companies: in the absence of other interventions, we will see a similar growth rate.  The key factor to significantly enhance the growth rate of these local industries is to marry with Proposition 2 – adding the academic and NHS infrastructure to provide efficient and streamlined offerings.
Valid	Scotland is unique and can offer a full-service package. The CROs are the best in the world and NHS Scotland is "comfortable" with this kind of work and these relationships.  There may be some confusion regarding 'diagnostics': The diagnostic companies are much more stand-alone - little reliance on TCM: it is the CROs which are the major players for Scottish TCM.
Valid	There is a strong link with diagnostics and TCM. As TCM activity increases in Scotland, there will be a parallel increase in diagnostics, so there is certainly strong growth opportunities.
Valid but with conditions	Requires much closer engagement between universities and companies
Valid but with conditions	Agree with the proposition, but TCM needs to link up the CROs and diagnostics. Difficulties in Scotland also stem from bureaucracy.
Valid in part	True, but more so for the diagnostics companies rather than the CROs.
Valid in part	Agree in general, but cannot comment on whether CROs and diagnostics will be the drivers.
Valid in part	Not wholly true. The CROs will grow on the back of the growing TCM agenda within the universities, NHS and SMEs.  Growth is restrictive for the CROs (and dependant on their parent company). There is not a critical mass of CROs in Scotland, and there have been a number of closures recently.  Similarly with the diagnostics, this will be linked to the growth of predictive medicines, driven by the big pharma.  Both CROs and diagnostics are competing on an international scale, therefore they are components of Scotland's TCM but not a driver.
Valid in part	Generally true: build the business base and the skills base will follow.
Valid in part	Generally agree, but although CROs support the TCM sector they alone are not sufficient for growth. And growth of CROs is not envisaged as being high in future.

Assessment	Company comment
Valid in part	But routes to growth a through a wider set of assets and opportunities in the medical Life Sciences: regenerative medicine, small molecule research, small scale feasibility studies, application of Scotland's capabilities in the application of medical technology/engineering and imaging

Source: SQW's primary research

5.20 The majority of consultees regard Proposition 1 as valid or valid in part. Our analysis and interpretation leads us to draw out the following points on Proposition 1 as being of greatest significance for the present study:

- despite an acknowledgement of their quality, doubts over growth potential of CROs and of their roles as divers/enablers of growth of TCM in Scotland
- polarised views over the appropriateness of linking diagnostic companies to the same proposition as CROs
- there is support for the proposition in terms of growth prospects in diagnostics, linked to the growth of predictive medicines driven by the big pharma.

**Proposition 2:** existing infrastructural developments (notably the NRS Permissions CC and SAHSC) will provide the opportunities for Contract Research Organisations to grow in Scotland. If valid, what is the scale of opportunities? Is more support need?

Assessment	Company response
Not valid	<p>Although not really familiar with the NRS Permissions CC and SAHSC, overall this narrative is too narrow with respect to CROs. The proposition assumes that all CROs are clinical, but in fact there are many 'non-clinical CROs': in Dundee for example there are CROs focusing on the 'discovery' area, plus service providers focusing on early stage safety activities and other CROs in manufacturing (CMOs).</p> <p>It is 'easy' to set up a clinical CRO with relatively little capital as the hospital essentially acts as the research host, whilst non-clinical CROs require capital investment in buildings and facilities as to CMOs for manufacturing.</p> <p>The challenge would be for SE to create incubator space for early stage drug discovery firms with Good Laboratory Practice (GLP) facilities and access to advice.</p>
Not valid	The universities are not equipped to interact with a commercial world and cannot see this changing. Universities have no leadership and no expansion plans that relate to business proposals. For example, the universities have no real concept of the drug development process or the relevant business environment.
Valid	<p>The CROs need a framework to work in.</p> <p>Cannot comment on scale and additional support.</p>
Valid	One should follow the other.
Valid	By developing the 'soft infrastructure (e.g. networks) this will present opportunities for clinical trials and the CROs – however, this is all still within the restricted growth opportunities for CROs.
Valid in part	Not knowing the full remit of NRS Permissions CC and SAHSC it was difficult for this consultee to provide a full answer, but feeling was that organisations such as SAHSC could <i>facilitate</i> growth: CROs will go where the demand is, rather than just being influenced by NRS Permissions CC or SAHSC.
Valid in part	Need the infrastructure married with industrial inputs.
Valid in part	This needs to be a consolidated approach with the development of other activities which lead to tenders – not just about CRO growth.
Valid in part	This may be true for certain types of CROs, but not all. The level of growth is uncertain.
Valid with conditions	NHS support and participation is restricted by available funds.

Assessment	Company response
Valid with conditions	They do provide opportunities and although international pharma may take them up, no sense that indigenous companies are making optimal use

Source: SQW's primary research

5.21 The majority of consultees regard Proposition 2 as valid or valid in part. Our analysis and interpretation leads us to draw out the following points on Proposition 2 as being of greatest significance for the present study:

- CROs as a group are not homogeneous – some focus on the pre-clinical some on the clinical; the different types have contrasting financing needs
- CROs are most influenced by demand for their services – the relevance of initiatives such as SAHSC to CRO's will be through increasing this demand.

**Proposition 3:** the development of biomarkers is the key route to enhancing the product portfolio and growth of Scotland's diagnostic companies. This will be achieved through: (1) outputs from the SAHSC working with pharma companies; (2) direct collaboration between pharma and Scottish companies; (3) strengthening commercial propositions through pooling IP from different sources and support initiatives

Assessment	Company response
Valid	Biomarkers are a development with a great emphasis currently. Whilst this firm is not currently involved in diagnostics this could provide a future growth area.
Valid	IP pooling could be the leading channel. It would be good if this could be contained within Scotland, but in reality it is likely to extend to the UK and beyond.
Valid	Way forward is to collaborate over biomarker work with pharma where possible. Consultee refers to the opportunities presented by funding from the Technology Strategy Board.
Valid	Yes but emphasis on diagnostics presents rather a narrow view – and “shouldn't limit to the ‘soft science’ route, include for example imaging”
Valid in part	The diagnostic companies can thrive regardless of the TCM in Scotland. However, their presence adds to the offering and medical heritage of Scotland.  Option 2, direct collaboration between pharma and Scottish companies is the most likely  Option 3 on IP pooling is a good idea. There is a lot of IP falling by the wayside.
Valid in part	Biomarkers are the buzzword of the moment all around the world, but in practice there is a real struggle for anyone to find the correct biomarker which is robust enough for their applications.  It will be big pharma which drive biomarkers in the future, either by developing their own in-house diagnostics or by acquiring smaller companies.
Valid in part	Biomarkers will become more important: perhaps SAHSC could drive the biomarker agenda. Perhaps big pharma will not drive this as it is more diagnostics-oriented.
Valid in part	Biomarkers are a big topic, with a lot of buzz, but biomarkers have been around for a long time  Almost all molecular targets (i.e. for drugs) need to be measured to ensure efficacy (i.e. is the drug reaching its target within the pathway) and is it interacting in the supposed manner for effective treatment. Each biomarker will be bespoke to the mechanism (pathway and specific target) This is still essentially experimental medicine.  Also, all governments internationally are trying to get big pharmas to buy into their academic and NHS-equivalent agendas.  One reason for big pharma interest is that many compounds have failed at Phase II: therefore there is a need for a better understanding of why these trials have failed - biomarkers may provide such evidence.  It will be big pharma and clinical centres that drive the development of biomarkers forward (for genetically different populations and ultimately for personalised medicines - in the very long term).
Valid in part	Biomarkers provide but one route: other routes will exist. It will be driven by all the named examples (1-3), but probably mostly by big pharmas; then by the nimbleness of small Scottish

Assessment	Company response
	<p>companies, and thirdly by IP flows.</p> <p>If Scotland is serious about this, there needs to be much more open IP network sharing : "realistically if Scotland is to benefit, then IP should be shared across Scotland".</p>
<b>Valid with conditions</b>	<p>Biomarkers will be important, especially at the level of individual drugs. However, this will rely on extensive networks for new biomarkers to be validated. Biomarkers have the potential to help reduce costs and shorten decision-making timelines. The biomarker can be pivotal in whether approval is granted or not for any drug.</p> <p>The consultee's company has used its own biomarkers for some a number of years, developed through its own clinical trials and so are regarded as 'robust'. However, many biomarkers are more generic and less well validated. Robust biomarkers are not mainstream yet.</p> <p>All three routes (1-3) will be applicable, but there are certain factors in play:</p> <p>big pharma will be needed to push biomarkers and the predictive medicines agenda</p> <p>the CROs will only follow the path taken by big pharma, therefore the CROs will not push biomarkers unless the pharmas do so first.</p> <p>the company developing the drug itself is best placed to identify a robust biomarker</p> <p>at this stage, there is no regulatory requirement for a biomarker on end-point drugs.</p> <p>New biomarkers need industry to provide the expertise, rather than just universities and NHS.</p>
<b>Valid with conditions</b>	<p>Biomarkers are a major opportunity for Scotland, with cohorts of patients in the main target areas. Biomarkers are a significant opportunity, but other opportunities will still exist – but Scotland needs leadership to take opportunities forward and exploit fully the commercial potential.</p> <p>Growth will be achieved predominantly through big pharma and other Scottish companies</p> <p>The 3<sup>rd</sup> option is highly unlikely, with the universities current position and their control of the IP</p>
<b>Valid with conditions</b>	<p>Biomarkers are key, and this is a global race.</p> <p>There are significant opportunities for Scotland – with IP needed for the best biomarkers for commercial exploitation. Scotland is at the forefront of therapeutic areas such as cardio and oncology, but concern that Scotland will lose out at the commercialisation stage. Having worked in the USA etc. this consultee is well aware that Scotland is very poor at commercialisation and marketing compared to peers in the USA and elsewhere.</p> <p>Extra support is needed in marketing new products.</p> <p>The drive needs to be within Scotland: if all products are licensed to big pharma this will just generate short-term gains for the economy but with no long-term benefits. Scotland needs to secure its own indigenous IP and to license in global IP from this global market. This will ensure gathering the most complementary IP and the best protection for Scotland.</p>

Source: SQW's primary research

- 5.22 All consultees regard Proposition 3 as valid or valid in part. The widely held view on the importance of biomarker development as a key route to business and economic growth is noteworthy.

**Proposition 4:** Scotland's current competitive position in TCM and its success in attracting clinical trials will prove a magnet for continuing foreign direct investment by both Contract Research Organisations and other companies with interests in TCM: this success in FDI will in turn attract equity investment.

Assessment	Company responses
<b>Not valid</b>	<p>Not convinced this is true. The Far East is ploughing vast sums of money in – it will be difficult for Scotland to keep up.</p> <p>Scotland will have to compete on its population size, patient records and a high morbidity rate – especially in cardio-vascular disease, but also emerging areas of interest such as Diabetes and Alzheimers (with Type II diabetes now being associated with Alzheimers).</p>
<b>Not valid</b>	<p>Not convinced that this is true – do not see this as a key driver or magnet.</p>
<b>Not valid</b>	<p>Have doubts on this. Some 60% of current R&amp;D budgets held by the pharmas and SMEs which was once conducted in the UK, has now transferred overseas, to the Eastern Block and Middle East etc. The UK is just left with small studies, but has the potential to do so much more.</p>
<b>Not valid</b>	<p>This is wishful thinking. The CRO market globally is currently in complete flux – in fact, the</p>

Assessment	Company responses
	opposite is more true, with CROs and investment gradually leaching out of Scotland.
<b>Valid</b>	If the clinical trials are secured in Scotland, then the demand will grow and the CROs and related inward investment will follow.
<b>Valid</b>	This has to follow – for any disease area. This may not involve major pharmas, but more likely to be low to mid-tier companies as well as indigenous SME growth.
<b>Valid in part</b>	With Scotland securing the presence of Wyeth, in turn taken over by Pfizer, there is proof of big pharma wanting to locate in Scotland. However, with the size of Scotland (population, ill volunteers etc.) the number of such success stories will be limited. There will be a cap on the size of the market.
<b>Valid with conditions</b>	<p>Scotland has already reached a critical mass with the presence of pharmas.</p> <p>SE also has good relationships with global pharma and is doing as much as it can. Using Wyeth as an example, it took over a Scottish business and decided to stay here. Pfizer has recently taken over Wyeth, and will continue to stay here – there is an attraction in Scotland. However, a greater physical presence of pharma is still needed.</p> <p>Proposition 4 will happen slowly and steadily, including through big pharma buying out smaller firms and retaining a local presence.</p> <p>At the moment there is a strong presence in Scotland of businesses in the pre-clinical stage, with the CROs. However, there is a gap further down the pipeline and a need for CMOs (Clinical Manufacturing Organisations) to move in and then for one of the big manufacturers to follow. It would only take 1-2 CMOs to move in for a big manufacturer to seriously consider Scotland as a location: “this is very possible within the next few years”.</p>
<b>Valid with conditions</b>	Important to differentiate between commercially sponsored, standard trials – in decline in Europe, and science-added trials
<b>Valid with conditions</b>	Links back to Propositions 1 & 2: strong infrastructure and industry presence (CROs & Diagnostics) will act as a magnet for further investment.
<b>Valid with conditions</b>	But this is not the “only show in town” – and should keep in view advances for the longer term associated with personalised medicine

*Source: SQW's primary research*

5.23 There are markedly mixed views on the validity of Proposition 4. A number of consultees argue strongly against the view expressed in the Proposition. Points we would pick out for emphasis are:

- doubts over the linkage between research discoveries and attraction of CROs to Scotland
- IP exploitation policies and access to risk finance remain important.

5.24 The diversity of views on aspects of these propositions is perhaps surprising given that they have been developed by SE with some industry input. Has this input been too ‘partial’ or is the situation so dynamic/fluid that views have changed? It is worth remembering that the companies contacted are ones nominated by the client. On the face of it, there remains a challenge to establish a common sense of direction for TCM in Scotland with the industry.

## Other assessments of the propositions

5.25 As with company consultees, we tested the validity and opportunities associated with the same four propositions when interviewing contacts in the universities, NHS and other public bodies. We summarise the responses on each proposition below. We do this by consultee: we have not distilled these responses too much as the individual qualifications are instructive. Each consultee’s response is set out in a single row of the charts.

- 5.26 Again it is relevant to note that three out of the four propositions give prominence to CROs. This accounts for the emphasis placed on these companies in the responses rather than any additional direction provided by SQW's consultants.

**Proposition 1:** the growth opportunities from TCM for businesses in Scotland (existing, new and/or inward investors) are likely to be associated with the growth of Contract Research Organisations and diagnostic companies. Any other opportunities?

Assessment	Comment
Not valid	Not sure that the focus on CROs is valid – “do they bring the type of business that is really needed?”  Doubts that contract research really the key – “what we need is strategic research and enhanced academic/health professionals/business collaboration.”  Refers to examples of better practice in Scotland in engineering and especially in Informatics.
Valid in part	This has happened, with examples of spin out companies resulting. However, significance of CROs here is less clear.
Valid in part	Probably a valid proposition although observes that diagnostic companies do not have much of a track record in Scotland so will need to be tested.  Also, the consultee would caution against over-emphasis on CROs – the need to attract “high quality researchers and entrepreneurs”.
Valid in part	Not sure on this – and unlikely to cause e.g. Pfizer to relocate to Scotland. Thinks emphasis is perhaps skewed: should be focusing on growing current CROs not trying to get new ones in.
Valid in part	Agrees that Diagnostic companies are important but not sure that Scotland needs more CROs. Important to convince those that are present to stay and grow (e.g. Quintiles) and that Scotland is the best business environment for them.  Also devices and device development is an important opportunity, building on existing university strengths. However, noted need to encourage use of devices in the NHS as currently little engagement here.
Valid with conditions	Possibly, but need much slicker connections between CROs and customers. Consultee noted that noted that Chiltern (Early Phase) Limited ( <a href="http://www.chiltern.com/cep/contact_us.html">www.chiltern.com/cep/contact_us.html</a> ) is located at Ninewells but in the opinion of this consultee its presence does not enhance university activity very much.
Valid with conditions	Possibly valid. But likely to be other opportunities so SE should not close its eyes to this possibility by over focusing on CROs and diagnostics.
Valid with conditions	Possibly valid, but worried that this proposition could lead to an over-emphasis on CROs and diagnostics. Need for companies to focus more on business on benefits of science.
Valid with conditions	Valid but CROs have “nothing to do with (driving) TCM”.

Source: SQW's primary research

- 5.27 There is general agreement with Proposition 1, but a number of informants question the significance of CROs implied in the statement.

**Proposition 2:** existing infrastructural developments (notably the NRS Permissions CC and SAHSC) will provide the opportunities for Contract Research Organisations to grow in Scotland. If valid, what is the scale of opportunities? Is more support need?

Assessment	Response
Valid	Huge investment in this. Are Business Development Managers in place at HEIs working together on the opportunities?
Valid	Have to assume this will be the case but more marketing needed, more financial support needed - need to package as pan-Scotland capability and present as such to the outside world.
Valid	Broadly agree: organisations such as Quintiles might grow as a result. However, this consultee noted that the initiatives referred to in the proposition could lead to HEIs doing their drug trials directly with pharma and as a consequence cut out the CROs – “a negative impact



Assessment	Response
	for the CROs but seen as positive for HEIs". More support could be given for national marketing to establish a more attractive 'shop window', but questions whether it will lead to more sales.
Valid	But estimate that the benefits will be marginal – "tiny".
Valid	But "no idea of potential scale of opportunities".
Valid with conditions	Still early days. Consultee is concerned at what appears to be an SE 'fixation' on CROs implied by the wording of the propositions – rather be dealing more with big pharmas/bio companies and developing strategic relations with them. However, recognises that more can/should be done to engage with and support the CROs that Scotland already has.
Valid with conditions	But needs a lot of support – "Scotland's biosciences brand needs to be addressed better." How is the brand being positioned with big pharma? This consultee has not seen any marketing material which would allow an assessment.

Source: SQW's primary research

- 5.28 In general there is broad agreement with Proposition 2. We would point to the following points as especially significant: one view that universities may do their own trials rather than procure them from CROs; the need for more marketing of the national 'offer'; and doubts over the scale of benefits that might be realised.

**Proposition 3:** the development of biomarkers is the key route to enhancing the product portfolio and growth of Scotland's diagnostic companies. This will be achieved through: (1) outputs from the SAHSC working with pharma companies; (2) direct collaboration between pharma and Scottish companies; (3) strengthening commercial propositions through pooling IP from different sources and support initiatives

Assessment	Response
Not valid	Methods of assessment to diagnose diseases more important than biomarkers. Also observed that biomarkers have many definitions. Most important for pharma is requirement to identify which drugs have a chance at Phase 3 and if no chance then need to abandon them quickly. IP pooling is "problematic" – "still a need to find common ground with pharma".
Valid	All valid, but highly dependent on success of SAHSC – "it will be central in supporting collaborative working". Next couple of years will be crucial.
Valid	But not convinced about IP pooling – "not seen much benefit from pooled IP yet."
Valid	Can envisage establishing "mini-Wyeth" type initiatives associated with developing collaborations between universities, the NHS and diagnostic companies
Valid in part	Constraints here include: uncertainty over whether SAHSC is really focussed on biomarker development; need for "extraordinarily selective scientific rigour – everyone has their own favourite biomarker".
Valid in part	Biomarkers increasingly important – "a key route but not necessarily the only route".
Valid in part	But according to this consultee: "a lot of rubbish talked about biomarkers - important to link biomarkers to asking the right questions".
Valid with conditions	Acknowledges significance of biomarkers, but emphasises the importance of cutting edge research/new technologies in order to apply them. Therefore need combination of strong research and good relations with pharmas – key objective of Bioquarter, also happening on lesser scale at Ninewells and Foresterhill. Company-to-company collaboration will also be important. Use of biomarkers in relation to stratified medicine rather than personalised medicine is of greater interest.



Assessment	Response
Valid with conditions	Biomarkers are important.  IP is important but noted that experience over IP issues with Wyeth had not been good – in part due to lack of movement on part of Cancer Research UK scientists on IP issues as much as intransigence on part of Wyeth. Hopes that all parties have learned useful lessons from this.

Source: SQW's primary research

- 5.29 In general there is qualified agreement with Proposition 3. However some important caveats were expressed on: feasibility of IP pooling; the extent to which SAHSC is focusing on biomarkers; and diverse views on the significance of biomarkers.

**Proposition 4:** Scotland's current competitive position in TCM and its success in attracting clinical trials will prove a magnet for continuing foreign direct investment by both Contract Research Organisations and other companies with interests in TCM: this success in FDI will in turn attract equity investment.

Assessment	Response
Not valid	Not convinced that just because discoveries are made here that CROs will necessarily come to Scotland.
Valid	This was the basis/rationale for TMRI – "still valid"
Valid	Scotland has an internationally competitive pharma R&D base  On constraints, the emphasis of research is perhaps moving away from TCM due to focus on hitting waiting times (for patients).
Valid	Scotland is positioned correctly to make this happen, but it is not occurring yet.
Valid with conditions	Yes but why this emphasis or restriction to CROs?
Valid with conditions	Generally agree, but emphasises the importance of VC availability - locally and in the rest of the UK it remains a key issue.  Questions whether SE has learned from the ITI episode and the perceived stumbling block of "outlandish IP deals" and a too near to market focus.  Agrees on need to have "serious pharma based in Scotland – don't have it at present".
Valid with conditions	Could be valid, but understands that Alexandria, in context of Bioquarter, was disappointed by extent to which equity investors currently interested in TCM in Scotland.  Scotland does not have an internationally competitive pharma R&D base at present. It has some niche players. But it could have one.
Valid with conditions	Still to prove that the rhetoric is true: there is still a need to improve recruitment and permissions issues for clinical trials.  It would be possible for Scotland to develop a sustainable internationally competitive pharma R&D base but it would need to "get all the things in place first".

Source: SQW's primary research

- 5.30 In general there is agreement with Proposition 4. However, a number of important caveats were raised around: Scotland actually delivering on its evident capability and opportunities (on the "rhetoric"); access to venture capital.
- 5.31 There is overall a greater degree of acceptance of the propositions from consultees from universities, the NHS and other parts of the public sector than from businesses.

## 6: Profiles of comparator TCM locations

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- 6.1 The Cooksey review of UK health research funding<sup>24</sup> recognised that other countries are facing similar challenges to the UK in increasing the successful translation of health research into health *and* economic benefits. The review noted that each country is tackling the challenges in different ways, with no overall ‘right answer’ which could or should be emulated in the UK, i.e. there appears to be no single ‘treatment’ of the problem that is readily transferable. What is also evident is that the ‘challenge’ has been attracting significant public investment in new facilities and collaborative ventures, including elsewhere in the UK<sup>25</sup>.
- 6.2 However, based on an examination of the situation in the USA, Canada and Sweden, Cooksey did suggest a number of critical success factors:
- *effective communication* between researchers at the various stages of health research and with those working in the clinical environments – developing a culture of mutual understanding, trust and co-operation
  - *effective leadership and communication* within individual institutions and in national/regional funding bodies
  - *reducing the complexity (multiplicity) of public funding mechanisms* – encouraging effective collaboration and coherent strategies of funding bodies whilst avoiding complex management and reporting structures
  - *adequate funding which helps ensure that researchers buy-in to the vision* – the translational agenda pursued but not promoted to the detriment of basic or clinical research
  - *research training for the clinical workforce* – developing a ‘research literate’ healthcare community which understands the value of research as an integral part of the healthcare system.
- 6.3 On the face of it, Scotland has been addressing a number of these issues in its own way e.g. strategic leadership through LiSAB and collaboration in the health research and clinical environments in various ways through TMRC, NRS and SAHSC. Our concern would be over the extent to which the business-base (beyond contributions to strategy development) views current TCM-related interventions as beneficial to them.
- 6.4 Profiles of comparator locations prepared during the present study are provided in Annex B. The locations investigated are:
- the Global Medical Excellence Cluster (GEMEC), UK
  - the London area

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<sup>24</sup> *Op. cit.*

<sup>25</sup> See for example the initial £600m investment proposed for the new UK Centre for Medical Research and Innovation at St Pancras, London, a partnership between the Medical Research Council, Cancer Research UK, the Wellcome Trust and University College London. (<http://www.ukcmri.ac.uk/news/press-releases/unprecedented-step>).

- Singapore
- Pennsylvania, USA
- Sweden
  - domestic east and west coasts
  - trans-national Oresund Science Region with Denmark.

6.5 We identify important learning points within Annexe B. Here we comment on issues that we consider to be of particular importance to TCM in Scotland:

- many areas promote and build on existing reputation and capabilities created over extended periods of time, including:
  - the history and ‘pedigree’ of people and institutions, commonly classed as world-leading in their field. – Scotland does the same
  - presence of renowned anchor organisations within the area e.g. academia, medical research hospitals and presence of multi-national corporations – Scotland does the same albeit its ability to showcase the latter is limited
- there is a strong emphasis on good governance structures for collaborative initiatives – Scotland promotes its track record in TMRC/TMRI:
  - there is common use of cluster and/or Triple Helix concepts<sup>26</sup> and implementation frameworks, with support from universities, hospitals, industry and government, and in places these are trans-national in scope
  - linked to this, there is close attention to networking and bottom-up approaches ( we do not wish to read too much into this, but in the course of this study no references were forthcoming to business networking mechanisms in Scotland)
- exploiting market potential facilitated by:
  - existing commercial strengths in the area, entrepreneurs, investors and multi-national company engagement – Scotland seems to focus largely on ‘Wyeth’
- realising future impacts enabled through integrated or ‘systems’ appreciation of contributions from:
  - financial capital (invested in infrastructure and enterprises)
  - from public and private sector sources, and from seed funds through to major FDI
  - human capital (labour pool, skills and volunteers for clinical trials)
  - knowledge capital (research excellence and invention)
  - understanding and alignment of regional and national systems of innovation.

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<sup>26</sup> The Triple Helix model is concerned with harnessing and leveraging the complementary expertise of academia, industry and government to facilitate new systems for innovation and novel collaborative processes.

- 6.6 It is notable that there remains a strong emphasis elsewhere on an integrated approach to economic development that uses ‘clusters’, ‘systems’ and related organising frameworks.
- 6.7 However, in general there is rarely a well articulated ‘theory of change’ or associated ‘logic model’ for strategies and interventions in these comparator locations that is made explicit in the public domain. There are lots of strategy documents and vision statements, and much promotional information, but much less readily available to investigate the links between strategy, its actual implementation and subsequent evaluation. The example of the Greater Philadelphia area may provide one ‘place’ where, with resource to investigate in more detail the public domain information, the true longitudinal pattern of development and impact might be determined. Underpinning all the reported “interconnected activity” in the Greater Philadelphia area is an “evolving support network for entrepreneurs, including venture capitalists, high-tech absorptive capacity, and providers of professional services.”
- 6.8 From the review of the Global Medical Excellence Cluster (GMEC) in England, there is a clear implication that even significant centres of excellence in their own right see advantages in collaboration to create ‘scale’. This collaboration is notable in involving several ‘big pharma’ companies, i.e. companies that otherwise compete in the market. It is difficult from the information that is readily available on the web to determine just how the collaboration works in practice: as SE knows from its experience with TMRC, there is much that needs to be in place behind the public marketing to make these collaborations work effectively.
- 6.9 Given Proposition 1 (see Section 5)<sup>27</sup>, it is instructive to note the references to CROs in the London Life Sciences strategy and action plan, 2003-2007<sup>28</sup>. Its focus on CROs was in order to “extend the value chain and support therapeutics”, i.e. it was progressed with key inter-dependencies in mind. The strategy document states:
- “The rationale for the selection of CROs – particularly clinical Contract Research Companies – as a niche area was based on London’s unique volunteer base, strong academic clinical research centres and strong company base. There is a critical mass of skills which are likely to migrate between these companies and the growth opportunities are significant given the global markets in this area. A significant feature of this selection was its potential to link with the therapeutics subsector to the mutual benefit of both areas. The business models of these companies (the CROs) also tend to require low levels of upfront investment, relying instead on retained profits, which balances the investment-based model that tends to dominate therapeutic development companies.”*
- 6.10 The implication here is that the economic development significance of CROs is in the role they perform within a wider, well-functioning therapeutics subsector addressing a global market. The CROs are not the ‘market makers’, but an important (and responsive) service component in an otherwise well functioning ‘system’. They succeed if other key parts of the ‘system’ (their market factors) are successful. It also indicates that access to finance, albeit from different sources of finance, is a key factor in development.

<sup>27</sup> i.e. that : “the growth opportunities from TCM for businesses in Scotland (existing, new and/or inward investors) are likely to be associated with the growth of Contract Research Organisations and diagnostic companies.”

<sup>28</sup> [www.lda.gov.uk/upload/pdf/BioLondonStrategy.pdf](http://www.lda.gov.uk/upload/pdf/BioLondonStrategy.pdf)

## 7: Monitoring and evaluation framework

- 7.1 In this section we comment firstly on matters relevant to monitoring and evaluation based on findings from this study - from the input from informants during primary research and from our own 'from first principles' assessment of the likely routes to economic impact based on the critical review of the existing TCM-related interventions. We then make specific recommendations based on SE's recently developed 'internal' monitoring and evaluation guidance and its 'menu' of measures. We provide detailed recommendations for each of the current TCM-related interventions in Annex A.

### Tracking routes to economic growth

- 7.2 Consultees from universities, the NHS and other public bodies were asked for their views on what are likely to be the main routes by which Scotland's TCM 'assets' contribute to economic growth: they were asked to identify key steps on the path that could be monitored and over what timeframe. The responses are summarised in Table 7.1 (with our *emphasis*).

Table 7-1: Routes to economic growth from TCM

Key route(s)	Responses
<b>Working with big pharma</b>	<p>Assets to be exploited are the size and stability of Scotland's population, and the ability here to undertake longitudinal studies (same is also true for Sweden and Norway).</p> <p>Relationships with big pharma companies is good; but overall better connections required – <i>need to capture and build on the key relationships that PIs have with pharma companies. These are not always exploited for the wider good.</i></p> <p>Consultee identified need for <i>an information base detailing who does what with whom.</i></p>
<b>Exploiting research and service reputation with businesses</b>	<p>Quality of service important, not just about research reputation –also about <i>service reputation</i>: need to be 'best in class' in all areas. Views of business 'satisfaction' with interactions with the TCM 'system' in Scotland are relevant here.</p> <p>Important to build this up over next 5 years.</p>
<b>Working with big pharma and building indigenous companies</b>	<p>Need to bring big pharma presence to Scotland plus indigenous company building (companies of value and scale)</p> <p>Cautious about estimating scale of opportunity.</p>
<b>Investment in education and training</b>	<p>Great emphasis needs to be placed on importance of education system as a route to achieving economic growth – without skills/development of young people then TCM suffers it as does not have <i>access to scientific/medical staff.</i></p> <p>Such excellent staff also have influence/reputation even if they leave Scotland through acting as ambassadors and through their own achievements. Therefore, important to "keep the faith in the education system" and continue to invest</p> <p>Time frame is 5 years or less to get TCM right – but a very competitive landscape.</p>
<b>Partnership working and a unified university technology transfer function across Scotland for the Life Sciences</b>	<p><i>Not yet translating TCM into economic growth, but neither are many countries.</i></p> <p>Development of effective partnerships is key to achieving this.</p> <p>Would like to see <i>one unified Tech Transfer Office for the Life Sciences across Scotland</i> as one of the first steps. This would give easier access to IP for companies, associated with lower initial costs for utilising it and agreement to deliver bigger returns upon success.</p> <p>Window of opportunity over the next 10 years.</p>
<b>Working with companies</b>	<p>Key route will be through the ability of the research 'system' (including academics) to deliver <i>'just in time' services to companies which previously may have had the expertise in-house.</i> The companies often no longer have access to this so now need to know where and how to access expertise and intellectual capital of the HEIs.</p>

7.3 From the above Table, the following tracking measures can be identified:

- *on pharma*: number of leads/prospects and value of collaborative and other contractual engagements with pharma companies
  - with Scottish universities, with NHS Scotland and with Scotland-based CROs
  - evidence of pharma ‘satisfaction’ with their experience of collaborations/contracts in Scotland
- *on company creation and growth*: number and valuation relating to indigenous company building
- *on educational “output” retention* – including take-up of graduates/post-graduates in non-commercial and commercial TCM work in Scotland
- *effectiveness of knowledge/technology transfer and exchange* – between universities and business (international and indigenous).

### **Relevant metrics for the economy and businesses**

7.4 For the purpose of tracking progress in TCM overall towards economic growth objectives *for Scotland*, we asked consultees what measures should be used. We also sought to identify those which are most relevant to business growth in Scotland. The consultees suggested the list in Table 7.2.

Table 7-2: Metrics for tracking overall progress in TCM towards economic and business growth

<b>Economic metrics</b>	<b>Business metrics</b>
<b>Jobs created</b> overall in TCM-related activities—sustainable and high value	<b>‘Standard’ knowledge exchange/transfer metrics</b> – see those used by Scottish Funding Council
Evidence of research and clinical <b>reputation/esteem</b>	<b>New company formation</b> – numbers, survivors, valuations/‘scale’
Level of <b>investment in research-base</b> – research grants and investment in facilities from external funding bodies	<b>Level of investment in new and existing businesses</b>
<b>Gross Value Added</b>	<b>Business turnover</b> – including income generated through attracting work for pharma companies
Level of <b>inward investment</b> – including attraction of firms to Scotland	<b>Business employment</b>
Level of all income to research-base generated from <b>work for pharma companies</b>	
Performance of TCM-related research in academic institutions – <b>Research Excellence Framework</b>	
<b>Attraction of high quality scientists</b>	
<b>Number and value of science added value trials</b>	
<b>Number and value of collaborative TCM activity</b>	
<b>Number and value of all trials</b>	
<b>Healthcare investment from external agencies</b> – benchmarked against other areas	
<b>Impact of TCM-related conferences in Scotland</b>	

- 7.5 One consultee from the NHS noted that if there is any monitoring of progress in TCM in Scotland at present, it is not being communicated well: “Even in the NHS clinical community there is not much information on what it achieves or how it adds value”.
- 7.6 From the inputs from consultees, the following additional activity, output and outcome measures are arguably similar to those that the Scottish Funding Council might consider in assessing the performance of its ‘research pools’: :
- *esteem*: sustained and increased academic and clinical esteem
  - *investment*: in research activities and facilities derived from UK and international sources through competition
  - *‘talent’*: evidence of attracting/retaining research, clinical and business talent.
- 7.7 Other measures of relevance are:
- *risk capital*: evidence of attracting risk investment to new or existing companies for the commercialisation of TCM-related projects
    - important to measure company quality (valuation) and sustainability not just numbers
  - *number of trials ‘offered’ to Scotland*:
    - important to acknowledge that the NHS responds to trials proposals brought to it. It would be relevant to measure the pipeline of opportunities as well as the trials actually conducted. This would be one way of assessing whether NHS capacity or other barriers are leading to lost opportunities
  - *number and value of clinical trials* – commercial and non-commercial (the latter as an early expression of ‘line of sight to market’ for translational research conducted in Scotland).

### ***Assessing progress for institutions***

- 7.8 In order to assess any important distinctions between approaches to tracking progress for the economy and for institutions, we asked consultees how their organisations assess their own progress and achievements in TCM. Consultees provided the following list:
- *research excellence* - now adopting the approach used in the UK Research Excellence Framework, but with the following additional comments:
    - as work gets more applied, it becomes more difficult to publish and therefore standard academic metrics become less applicable.
    - one university consultee noted that the institution has introduced a Clinical Practice Impact Plan, but regards it so far as a ‘shot in the dark’
  - *medical outcomes*: for the NHS the focus is on metrics relating to patient care and health outcomes
  - *miscellaneous other metrics referred to include*:



- generation of IP
- ones associated with new drug discovery leading to improved patient care – but with acknowledgement of the difficulty of tracking impact back to original research due to extended timescales
- grant income
- infrastructure developed and available
- participation in clinical trials
- number of ‘quality’ papers produced
- number of people trained (including those given TCM-related business training)
- technology transfer/exchange metrics - including disclosures, patents, licenses
- companies formed and sold - valuation of those companies
- measures of collaboration with partners.

## Assessing economic impact and associated measures

7.9 SE has now developed a template for a monitoring and evaluation plan. We have used the components of this template in developing this design checklist in Table 7.3. Throughout we seek to respond to what we understand to be SE’s key focus on the performance of companies operating in Scotland.

Table 7.3: Monitoring and evaluation framework – design checklist

MEASURE	WHAT?	WHEN?	WHO COLLECTS?	HOW REPORTED?
MONITORING:				
Inputs	- the measures that need to be monitored	- how often each individual measure should be monitored	- who should be responsible for collecting the information	- how/to whom should the information be reported
Activities				
Outputs				
Outcomes				
EVALUATION:				
Assessing all matters set out in Table below	- interim review	- when should an interim review be undertaken	- who will be responsible for undertaking the review.	- how/to whom should the information be reported
Assessing all matters set out in Table below plus net GVA impact	- full impact evaluation	- when should a full impact evaluation be undertaken	- who will be responsible for undertaking the evaluation.	- how/to whom should the information be reported

Source: adapted from SE guidance, May, 2010

7.10 The feedback above from primary research was in response to questions about support for and progress in TCM generally in Scotland. Earlier in this report we identified the potential routes to economic impact likely to be associated specifically with each of the existing interventions. We return to these in Annex A where we make detailed recommendations on the measures that

could be used to monitor progress for each of the existing TCM-related interventions (and by whom) and to evaluate impact.

### ***Towards a coherent approach***

- 7.11 Of course, for SE we see merit in metrics which provide ‘lead’ indicators of future desired outcomes and impacts, e.g. measures of lead/prospect development, invention disclosures and conduct of feasibility studies/early stage trials associated with translational research.
- 7.12 For the TCM landscape overall, we would recommend a basket of measures (perhaps ‘owned’ by the Scottish Funding Council) which would give assurance of the sustained quality and international competitiveness of the TCM-relevant research base. This takes a long time to develop and underpins much of what makes Scotland, as a small country, ‘notable’ internationally. Given the importance of collaboration within the research base, we would advise examining key performance indicators (KPIs) used in the tracking of the effectiveness of SFC’s research pools.
- 7.13 Secondly, we would advise a basket of measures focused on the performance of indigenous SMEs, new and existing. We see three strands to this: (i) measures relating to activities and benefits associated with SME-to-university (and NHS) links – this needs to focus on ‘outcomes’ achieved not just activity measures; (ii) measures relating to SME-to-commercial customer (pharma) links (engagement opportunities as well as commercial outcomes); and finally (iii) SMEs and their access to risk finance, including from UK and internationally competitive sources.
- 7.14 It can be argued that the access to risk finance measure is a key measure of ‘quality’ of the business and scale of addressable market opportunity being pursued (perhaps the ‘owl in the forest’).
- 7.15 Thirdly, we would advise a basket of measures (perhaps ‘owned’ by the CSO) that captures issues associated with the achievement of patient outcomes achieved through translational activities. Given that benefit to patients is a crucial motivation for certain key staff especially in the NHS, it will be important that the benefits of engaging in TCM are made visible to all interest groups.

### ***A counter view***

- 7.16 The counter view put to us in feedback is that some funders already measure the impact of the research they fund, albeit to varying degrees; that measurement is notoriously difficult given long lead-in times; and in any event few pieces of research by themselves produce a clear outcome leading to change, as distinct from contributing to the knowledge base. Given that it may take extended time scales and significant resources to map and count progress, it was not clear to this informant who would benefit.
- 7.17 Notwithstanding this counter view, the issue was raised in the Cooksey in the review of UK health research funding<sup>29</sup>:

*“Several of the responses to the consultation called for new systems or methodologies to underpin the systematic review of existing research. There was also a call for a systematic review of existing evidence on the impact of healthcare research on health and healthcare.*

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<sup>29</sup> Op. cit. p. 40

*Recently, the Academy of Medical Sciences, MRC and Wellcome Trust issued a report on the evaluation of medical research, calling for improved and more consistent methods of evaluation.”*

- 7.18 Throughout the Cooksey review, reducing time to the realisation of health benefits is a recurring theme. It notes<sup>30</sup>:

*“The idea is to develop new discovery technologies which will speed up the drug discovery and development process, right up to licensing. For example, this might involve identifying new ‘end points’ or ‘biomarkers’ in clinical trials which would act as a proxy for proof of efficacy and/or safety and therefore shorten the time needed to bring safe new drugs to market. A UK strategy here will need to take into account the relative strengths of the UK and other countries in this broad area, and focus on UK strengths. For example, the UK is in a comparatively strong position to develop tools to enhance predictive toxicology (e.g. using stem cells), which could reduce drug attrition rates at the clinical trials stage, where costs to industry are highest.”*

- 7.19 What is being proposed by SQW above is a holistic approach to medium term monitoring of progress for medium to long term benefit which would involve SE and partners. We are aware of SE’s particular, focused role and interest: the measures associated with SMEs above are in recognition of this. However, success in TCM nationally requires a systemic approach, engaging a wider range of parties, with different motivations/incentives and roles, positioned along the ‘value chain’. The volume and quality of activity and outputs associated with TCM will underpin the economic benefit to be derived from the inputs to TCM in Scotland. Given the inter-dependencies, SE may not wish to ‘own’ all the measures (e.g. measures of research income, academic esteem and impact of research papers) but all will be influential in determining the fate of the TCM-related business base in Scotland over the medium to long term.

## Adopting SE’s protocols

- 7.20 In May 2010, the client provided SQW with new guidance from SE on the design and implementation of such a framework. The design of practical procedures for use with TCM initiatives has therefore followed the new guidance, making use of the ‘workbook’ supplied with the guidance as a menu from which to extract SE-approved and TCM-suitable measures.

### **Background and principles**

- 7.21 The purpose of the new guidance is to provide SE, and its partners, with a framework within which to “systematically collect and review key information that will inform the future strategic direction of project development and assist in the design and delivery of future policy”.
- 7.22 The strategic context and direction of interventions falling within the framework are provided by the GES launched in 2007 and its five strategic priorities for sustainable growth, namely:
- *Learning, skills and wellbeing* – a skilled and educated workforce is essential to building competitive advantage and sustainable economic growth;
  - *Supportive business environment* – creating the best possible environment for competitive businesses, entrepreneurship and innovation to flourish;

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<sup>30</sup> Op. cit. p. 112

- *Infrastructure development and place* – investment in the physical and electronic infrastructure and Scotland’s planning development and funding framework;
- *Effective Government* – a more effective government focused on sustainable economic growth and streamlining the government’s dealings with businesses; and
- *Equity* – creating the conditions for growth and cohesion together with enhancing the environment.

- 7.23 In the context of SE’s objectives and interests as set out in the brief for the present study of TCM, the priority area of ‘supportive business environment’ is the most relevant.
- 7.24 Notwithstanding business activity and inward investment that may benefit Scotland in the short term as a result of SE’s contribution to TCM (e.g. attracting clinical trials due to the reduction in time to gain ‘permission’ for trials already achieved by the NRS Permissions CC; the recently announced decision of the drug development company TPP to locate to Edinburgh Bioquarter), much of the potential benefit to the economy from TCM needs to be considered beyond the term of SE’s current Business Plan (to 2013)..
- 7.25 In the context of SE’s objectives and interests as set out in the brief for the present study, success in TCM through indigenous business growth and inward investment will be the main areas with potential to contribute to the GES strategic targets. However, TCM, through innovation in diagnostics and therapeutics relevant to the healthcare of people in Scotland, can also contribute to the longer term targets for the healthy life expectancy of the population and to labour productivity. The significance of TCM for health outcomes is of course central to the mission of the NHS and its staff: it can also be a key motivation for researchers in universities, research institutes and company laboratories.

### ***Proposed monitoring and evaluation framework***

- 7.26 SE’s approach to designing a monitoring and evaluation framework is described in a newly developed ‘workbook’ (Version 1.3: May 2010) which includes what is essentially a menu of approved measures. Tables 7.4 to 7.7 are populated with and provide a commentary on those measures specified by SE’s new guidance that we consider to be of greatest relevance to TCM-related activities, outputs and outcomes overall. (As indicated earlier, intervention specific recommendations are provided in Annex A).

Table 7-4: 2010 – 2013 Performance Framework

Measure Description	Target Setting	SQW Comment
<b>No of businesses completing projects within:</b>		
<ul style="list-style-type: none"> <li>innovations: implementing new products, services and/or processes</li> </ul>	Needs to be based on a percentage of the potential 'market size' in terms of numbers of relevant companies.	Relevant directly to SHIL and to Bioquarter. Otherwise relevant to commercialisation outcomes of TMRC and SAHSC.  Responsibility: SE with intervention leads.  Time: monitor at least 6 monthly and evaluate every 2 years
<ul style="list-style-type: none"> <li>internationalisation: potential to significantly increase international revenue</li> </ul>	Needs to be based on a percentage of the potential 'market size' in terms of numbers of relevant companies looking to export.	Not directly relevant to any of the current interventions although, from primary research evidence, for many TCM-related companies export success is crucially important.
<b>No of planned high value jobs from businesses completing inward investment projects:</b>		
	Needs to be established from an understanding of the number of leads and prospects, and their conversion into 'projects' whose plans can be ascertained and supported.	Especially relevant to Bioquarter but also to SAHSC's aspirations to attract inward investment.  Responsibility: SE with intervention leads.  Time: monitor at least 6 monthly and evaluate progress every 2 years
<b>No of businesses either starting up or completing projects with significant growth potential as a result of SE commercialisation or high growth start-up activities:</b>		
<ul style="list-style-type: none"> <li>of which commercialisation propositions with the potential to achieve £5m of revenue within 5 years</li> </ul>	Needs to be based on a percentage of the potential 'market size' in terms of (a) numbers of relevant companies looking to commercialise IP, and (b) the flow forward from invention disclosures, feasibility studies and from pre-clinical trials involving the research-base.	Especially relevant to TMRC, SHIL, and future SAHSC generated programmes, and Bioquarter.  Responsibility: SE with intervention leads.  Time: monitor at least 6 monthly and evaluate every 2 years
<b>Investment in Business R&amp;D from SE assisted projects contracted during the year involving R&amp;D and SMART grants</b>		
	Needs to be based on a percentage of the potential 'market size' in terms of numbers of relevant	As above.  Not directly relevant to any of the existing interventions but certainly relevant to the development of the TCM-related business base overall.

companies.		Not directly relevant to the existing interventions but certainly relevant to the development of the TCM-related business base overall and especially to commercialisation of TCM-related IP.
<b>Leverage resulting from SE investment funds</b>		
<b>Investment leverage in physical infrastructure resulting from high impact projects</b>	Needs to be based on a percentage of the potential 'market size' in terms of numbers of relevant companies.	
	Patterns of equity investment in diagnostics elsewhere could be examined for comparison.	
<b>Turnover growth by businesses supported (through account managed activities)</b>	Could be benchmarked against prior experience.	Relevant to Bioquarter. Responsibility: SE with intervention leads. Time: monitor at least 6 monthly and evaluate progress every 2 years
	Needs to be based on a percentage of the potential 'market size' in terms of numbers of relevant companies that are eligible and that are account managed.	Not directly relevant to any of the current interventions but relevant to the development of the sector overall.
<b>No of projects which lead to the commercial exploitation of intellectual assets</b>		
<b>No of projects which support industry wide development including:</b>	Key factor is what constitutes a 'project'.	Highly relevant to all existing interventions except for NRS Permissions CC. Responsibility: SE with intervention leads. Time: monitor at least 6 monthly and evaluate progress every 2 years
	<ul style="list-style-type: none"> <li>industry strategy and leadership</li> <li>business collaboration</li> <li>infrastructure to enable sector growth</li> </ul>	Relevant to all existing interventions. The level of business engagement in collaboration is especially important to assess.  Responsibility: SE with intervention leads. Time: monitor at least 6 monthly and evaluate progress every 2 years

**Forecast revenues, including exports, (£m) from projects completed during the year**

Export is not directly relevant to the existing interventions although export is crucial to the success of many of the businesses consulted in this study

**Planned jobs from projects completed during the year:**

Relevant to all the interventions. Important to confirm if only jobs in the private sector are counted as present interventions may be safeguarding/creating most jobs in universities.

Responsibility: SE with intervention leads.

Time: monitor at least 6 monthly and evaluate progress every 2 years

It would be relevant from now to know how firms associated with TCM perform relative to other parts of the business base and to use these kinds of measures relative to overall level of SE's inputs to TCM to gauge 'value for money' over time.

- created (high value and other)
- safeguarded (high value and other)

See earlier note about the likely need to differentiate where jobs are created – in the research-base with industry funding or in the business base.

From this study, it is clear that jobs safeguarded are especially important in the CRO sub-sector.

**No of businesses supported (by category)**

This a relevant measure from now to test how relevant SE's support is to firms involved with TCM – what market size, what need, what uptake? It is not clear the extent to which interventions such as TMRC and SAHSC have been designed to benefit indigenous business beneficiaries

**Annual turnover growth, inc exports and social economy, and annual employment growth**

This a relevant measure from now to test how relevant SE's support is to firms involved with TCM – what market size, what need, what uptake? Again, it is not clear the extent to which interventions such as TMRC and SAHSC have been designed to benefit indigenous business beneficiaries.

It would be relevant from now to know how firms associated with TCM perform relative to other parts of the business base and to use these kinds of measures relative to overall level of SE's inputs to TCM to gauge 'value for money' over time.



Table 7-5: Industry strategy and leadership - identify opportunities and act as the catalyst to ensure sectors take full advantage

Activities: Industry – Sector-based	SQW Comment
<ul style="list-style-type: none"> <li>Up-to-date industry strategies in place</li> <li>Fully functioning Industry Advisory Groups in place</li> <li>No of industry networks, industry associations or intermediary bodies supported</li> <li>No of strategic industry collaborations</li> <li>No. of initiatives to enhance international perceptions of industry</li> <li>Number of account managed for growth businesses in each sector</li> <li>Annual turnover growth of account managed for growth businesses in each sector</li> </ul>	<p>We agree with the relevance of these activity measures of sector development but they are only relevant to the extent that they can be shown to be delivering firm-specific benefits that then translate into a contribution to economic growth.</p> <p>From an SE perspective this evidence of benefit is, from our reading of the 'workbook', expected in the short term to be shown through the number of SE products being delivered through industry projects and over time through evidence of (i) "increased activity" within the sectors as a result of SE activities and (ii) "increases in businesses being assisted through industry projects and/or intervention framework delivered products".</p> <p>Collaborations with companies (including international companies/potential inward investors) over e.g. research and doctoral training schemes are relevant here in establishing and sustaining strategic partnerships.</p> <p>Initiatives such as continuing success in attracting industry-relevant international conferences to Scotland is one relevant way of influencing perceptions.</p> <p>The profile of TCM-related participation (segmented by type of company – CRO, diagnostics etc.) in the account management scheme is a relevant measure.</p>

#### Outputs: which led to Outcomes

The following is extracted from the 'workbook': "Delivery of SE products to businesses should lead over time to outputs from the creation and delivery of development projects within internationalisation, innovation and/or business efficiency".

In the context of the industry-sector measures discussed above, we would make the following contrasting point: the activities set out above should lead over time not only to enhanced take-up of SE products for firm-level support but also to an industry which is better able, including through collaboration, to adapt successfully to new and emerging opportunities and threats, and through industry-driven mechanisms to assume a leadership role – and therefore enhance competitiveness and growth.

Table 7-6: Business collaboration - engage directly with or support business and academia to collaborate

Activities: Industry – Sector-based	Comment
No. of businesses participating in SE supported key industry events	This activity metric to capture firm-level engagement can be used to check the relevance of SE's approach to TCM-related developments.
No. of collaborations (businesses only)	This is not something that is a feature of the objectives of the current TCM interventions,
No. of collaborations (businesses and academia)	

We fully endorse the statement made in the 'workbook' on the: "Need to ensure that this measure does not stop at the activity level".	
Outputs: which lead to Outcomes	
Concept testing/feasibility studies and pre-clinical trials are examples of academic-business collaborations that can deliver outputs and valuable (intermediate) outcomes.	
Commissioning of CROs to assist in the commercialisation of academic research may be another form of 'collaboration' as may the collaborations which seem to be envisaged with university researchers in the recently announced investment by the drug discovery company TPP in Scotland.	

**Table 7-7: Infrastructure to enable sector growth - supportive business environment to nurture sectoral growth**

<b>Activities: Industry – Sector-based</b>	<b>SQW Comment</b>
Industry intelligence / research produced	The take up of this support by TCM-related companies is a relevant measure.
No. of businesses using key industry research/information reports	The level of take up coupled to subsequent assessment of business satisfaction and 'value' would be a means of assessing interest and relevance. The absolute number is a useful check on interest/demand relative to other business sub-sectors and may be used (if low) to trigger an assessment of relevance and quality.
No. of businesses utilising foresighting reports	
No. of SE supported key industry events	
Physical infrastructure investment leverage	Measures relating to leverage on investment funds have been referred to above as one way of assessing 'quality' (attractiveness to investors) of TCM-related projects and firms.
SE investment funds leverage	
Outputs: which lead to Outcomes	
It is arguable, that achieving leverage on investment, assuming it to be of a reasonable scale, is actually an outcome rather than an 'activity' - and an outcome that confers an important sense of the market attractiveness of the investment proposition.	

7.27 In general, we are happy, with certain caveats, to concur with the distinction made in the SE ‘workbook’ between:

- interim review, which focuses on:
  - market failure assessment
  - strategic fit
  - operational effectiveness
  - assess future direction
- full impact evaluation, which covers:
  - market failure assessment
  - strategic fit
  - operational effectiveness
  - impact assessment
  - assess future direction.

7.28 We suggest exploiting more explicitly the learning opportunity presented by the interim review to re-assess the underlying ‘theory of change’ – the envisaged linkage between what the intervention actual does and delivers as outputs and the outcomes it has or is likely to achieve. This can lead for example to an adjustment of the monitoring frame to ensure that the outcomes can be fully appreciated or it may cause a fundamental re-think of the logic embedded in the business case.

## 8: Conclusions and recommendations

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- 8.1 In the course of our primary research we sought ‘suggestions’ from consultees on how SE could help support the improvement of the TCM landscape in Scotland. We begin this section by summarising the views of businesses and other stakeholders. We then provide our conclusions and recommendations in response to the objectives set for the study.

### Views from business

- 8.2 Interviewees were asked for their suggestions on how to enhance the business environment in Scotland: (a) specifically for their company and/or (b) for achieving economic growth through exploiting Scotland’s R&D capabilities in TCM. The narratives below summarise the inputs received from businesses:

- *all the pieces of the jigsaw are present*: it is crucial for SE to continue to encourage the various parties to work collaboratively to provide a “full fit”. The quality of research is high, the NHS and access to patients is good, and the “world’s best CROs” are present. Scotland is unique in this: however it needs SE and others to add more value, e.g. by as bringing CMOs into the mix and streamlining processes and regulations
- *centres of excellence*: still a need to develop the mechanisms that can bring all the various parties interested in TCM together, for example by establishing R&D and/or manufacturing centres
- *support large companies*: one consultee expressed opposition to the funding of smaller companies only. Having looked at other countries (e.g. USA), it is argued that there is an abundance elsewhere of money/grants for infrastructure, staff training etc. If Scotland is serious about wanting to grow TCM, then there needs to be incentives for the larger companies as well. “If a large company was to grow 10% that could be 100 people, for an SME it may be one additional job”
  - SE should work to attract/retain the presence of medium to large pharmas and biotech companies, as well as supporting the development of more SMEs. Together these will facilitate the translational steps through R&D, clinical trials and biomarker development
- *enhance marketing*: there is perceived to be a lack of visibility and lack of information within the business base on how to access the existing TCM initiatives. Communication of their relevance to indigenous businesses needs enhanced
- *funding*: access to finance is seen as a “big issue”, with one consultee arguing that SE is too risk averse whereas TCM by its nature is generally a high risk area. Additionally, a perception is that SE do not seem keen to fund projects close to market as is the case for TCM

- *SE/MRC relations:* SE should explore links with MRC to strengthen commercialisation capabilities for of medical R&D.
- *reality check:* perspective is required: one consultee argues that in an international context, the sums that SE provides are “absolute buttons – it wouldn’t last our site for six months”. Therefore, the limited funding must be targeted very carefully to capitalise on Scotland’s strengths
- *influence:* important for the public sector to know better who to influence in the industry and to focus on the priority disease areas of the country (i.e. cancer, diabetes, obesity etc) and towards better experimental medicine. SE encouraged to develop much stronger relationships with the larger companies with a presence in Scotland if the scientific environment is to be fully exploited.
- *business/NHS relations:* closer collaboration encouraged between businesses and the NHS, rather than only a fee-for-services relationship

8.3 On trials, one consultee argued that with the increasing number of academic units researching into drug discovery, there needs to be much closer collaboration with the commercial sector for these early stage (“commercially unattractive”) activities. This would share the risks and expertise (scientific and business process) and make better use of finite resources to accelerate compounds into clinical trials with a shared (IP) ownership. Moreover, it allows a greater volume of compounds to be tested. As only a small number of compounds may be successful, the greater throughput increases the odds of achieving success. “If Scotland is serious about translational science, then high levels of collaboration throughout the process must be achieved.”

8.4 However, another consultee was less optimistic: he does not think that SE can really do anything that will have significant beneficial impact on his company as it is operating within a global environment. Investment decisions are made on a global basis and location is only a small factor. Tax regimes do have an effect on the decision-making of businesses at a global level, but not an issue for SE.

8.5 Others did see an ongoing role for SE. One key activity is associated with facilitation rather than just funding: “Activities such as this current study by SE/SQW needs to be collated, key projects identified and used to help bring everyone together”. Pushed for a specific example, the consultee wished to see greater SME integration into the TCM arena/ network. SE should be able to access all companies (SME and large) with relevant capabilities in Scotland, to map out the expertise and plot this with the capabilities and interests of the universities and the NHS in Scotland. This will provide a structure and roadmap for Scottish TCM. Linked to this there seems to us a clear implication for enhanced communication with the business base on the nature and relevance to them of the investments being made by SE and by other parts of the public sector in Scotland in TCM-related initiatives.

8.6 A number of consultees pointed to the valued financial support from SE that their firms had already received. One suggested that companies in Scotland may well be some of the best supported anywhere in the world! There is also an appreciation of the “fine balance” between spending public money and getting a good rate of return on investment.

- 8.7 We developed a strong sense that SE still has work to do to encourage industry leadership and action, working pro-actively and in partnership rather than SE ‘owning’ all the challenges that are faced.

## Views from ‘stakeholders’

- 8.8 Consultees from universities, the NHS and other public bodies were also asked to make suggestions on actions that should be taken to improve the environment for TCM in Scotland. A number of ‘challenging’ suggestions were made which we report here whilst acknowledging that many would require further investigation to validate their attractiveness and feasibility, and where justified develop appropriate actions:

- *re-enforce strengths*: important to build on existing TCM strengths, not always construct new things, and important to facilitate still closer partnership among providers of TCM research.
  - reference to other countries/institutions which seem to “do it better” e.g. Singapore ([www.pharmaceutical-technology.com/projects/biopolis/](http://www.pharmaceutical-technology.com/projects/biopolis/)); Glaxo institutes in HEIs; Novartis Institute: ([www.novartis.com/research/nibr/index.shtml](http://www.novartis.com/research/nibr/index.shtml))
- *enhance access to records*: there are outstanding opportunities through the exploitation of patient-derived records: Scotland has an asset here which would be attractive to pharma companies, but “they are currently inaccessible”. This is not regarded as a legal/ethical issue, simply an organisational one: “perhaps a role here for TMRI?”
- *people mobility*: merit in doing more to encourage talent exchange between pharma and academia. A second consultee expressed this as the need for a mechanism which eases transition of NHS Consultants and academics in and out of industry
- *marketing*: Scotland could do more to present a professional shop window for TCM (example given of ‘meeting and greeting’ international visitors at airports) – “other countries do it better”
- *infrastructural investment*: local infrastructure issues need fixed – example given of transport links to Bioquarter
- *backing winners*: SE is advised to give further attention to “how winners are backed”. This consultee asks if SE can really continue trying to “placate all parties” – “there is a genuine East/West divide”. According to this consultee: “If Scotland is to succeed in this area then SE (and others) needs to be more honest and support certain areas, acknowledging where true world class expertise/opportunities lie.”
- *fit-for purpose capacity*: one consultee posed a question that arguably goes beyond SE’s remit but is reported here for completeness: “ at some point a decision will need to be made as to whether all four Medical Schools are needed: does Scotland need/ can it afford all four? Need to be honest and play to strengths.”

- *IP management*: there is a need to revise the model for local IP capture – “not convinced it is working well through SHIL”
  - also problems associated with IP issues need to be addressed as they can still constrain NHS- universities attempting to work together: there is a need to understand and develop better structured protocols to establish what IP is present/being generated, who owns it, how it is generated and how resultant benefits are to be attributed
- *prioritisation*: a focusing down is needed on priorities – “what is core business, what are core priorities?”
- *follow through*: one consultee argues that sometimes SE “makes lots of suggestions whilst offering little material support”. There is a need for a tighter implementation plan
- *incentivising collaboration*: there is a need to reward collaboration much more than is done at present – currently the academic system is designed to reward institutions collaborating *and* competing
- *leadership*: stable and more effective leadership required with closely industry involved
- *threat of funding cuts*: one consultee expressed a serious concern over the Scottish Funding Council’s plans for considerable reduction in its formula-driven Knowledge Transfer Grant: “this will prove to be counter productive and act as a disincentive as far as institutions’ involvement in TCM activities are concerned as it will remove any levers that there are for making the case internally (within a university) for continuing investment in TCM”.

8.9 The positioning of SE relative to other public sector and university stakeholders in TCM needs in our view to be re-assessed and placed on a firmer, more explicit footing. A number of the issues raised above are indeed likely to have an important bearing on the future success of TCM in Scotland but appear to lie within the remits of other public bodies.

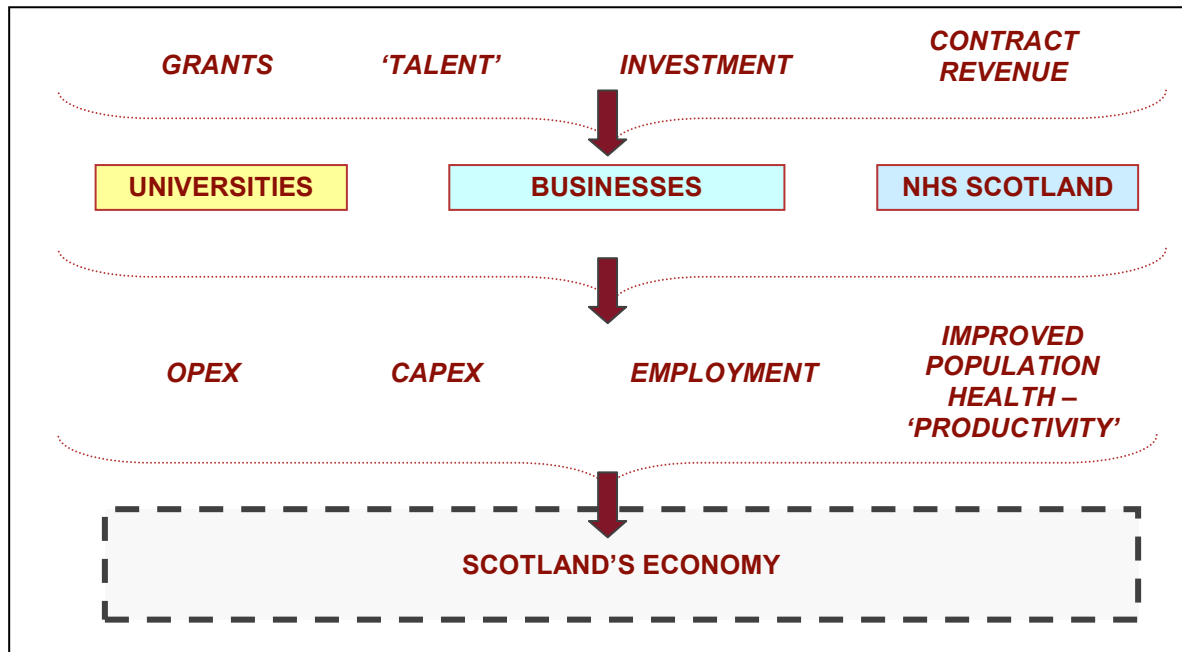
## Summary of conclusions

### ***Routes to impact***

8.10 Figure 8.1 provides a conceptual framework for the potential routes to impact. A range of inputs to TCM can be identified that work through to impact, but not all directly via the Scottish business base.

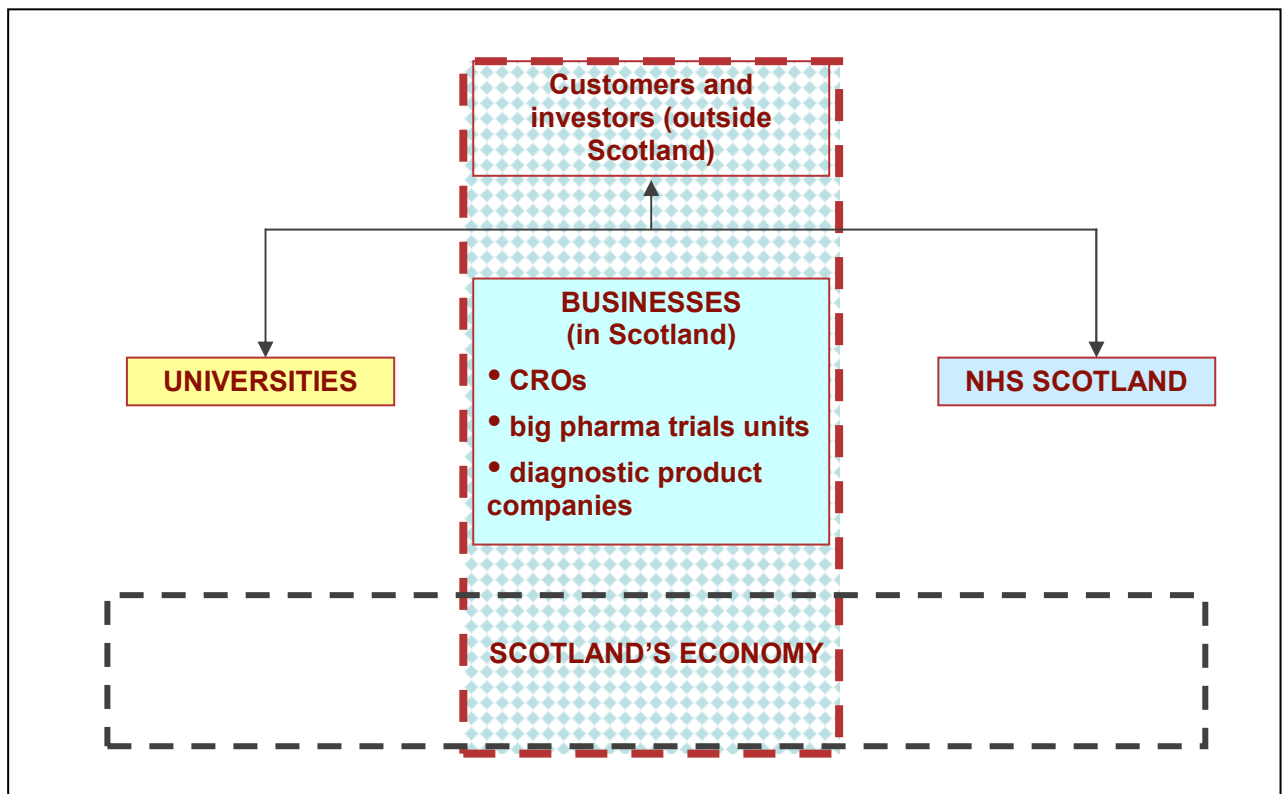


Figure 8-1: Routes to economic impact - principles



- 8.11 Arguably, SE's interest is in those routes that directly or indirectly have a beneficial effect on the business base (Figure 8.2).

Figure 8-2: Routes to economic impact – SE's focus



- 8.12 Whilst there was a broad consensus around the quality of CRO capability in Scotland, the potential for significant future growth of business for them in Scotland was less clear cut. Taking a wider perspective, the changes in the business models of large pharma companies and their increasing interest in business opportunities offered by emerging markets (i.e.

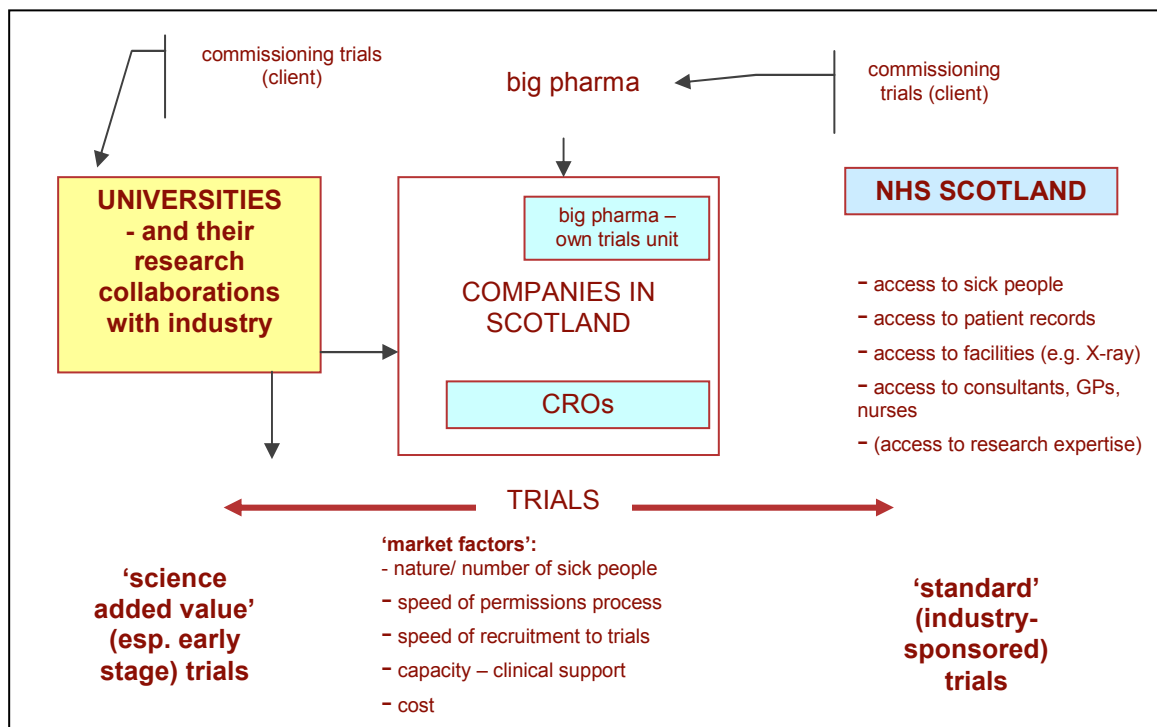
outside of Europe and North America) may bring growth opportunities for those CROs with an international reach.

- 8.13 The business strategies of big pharma towards predictive medicine are also like to be important in terms of determining growth opportunities for diagnostics companies. Some consultees suggest that pharma companies may develop in-house diagnostics development capability whilst some may rely more on acquisition of smaller, specialist firms. Outsourcing/strategic relationships may also develop. The vision for the TMRC is ‘to create a world class centre of excellence in biomarker discovery and utility’. Although some informants suggest that strengths in biomarker development in Scotland will continue to act as a magnet to attract investment, another argued that the healthcare re-imbursement model in the USA is likely to make opportunities there much more attractive to investors. Notwithstanding this caveat, there is general support for the proposition that biomarker development will prove to be a key route to business and economic growth for Scotland.
- 8.14 We also encountered quite divergent views on the positioning of diagnostics companies within the ‘system’ in Scotland: ‘diagnostics companies are more stand-alone (than CROs) in terms of their position in TCM in Scotland’ and ‘there are strong links between TCM and diagnostics – within growth in TCM there will be a parallel growth in diagnostics’.

### **Progress and future impact**

- 8.15 On progress to date and likely future impact of current TCM-related interventions supported by SE, we conclude the following:
- substantial achievements in enhancing collaboration within and between the academic sector and the NHS have been made (e.g. TMRC, NRS and SAHSC)
  - the collaboration that attracted Wyeth and formed the TMRC/TMRI was a notable achievement
    - however, in both of the above, significant benefits for the indigenous TCM-related business base are yet to be seen
  - the NRS Permissions CC appears to have made good, early progress in achieving efficiencies in NHS procedures for approving multi-centre trials
    - the added value specifically for indigenous CROs over competitors is yet not clear
  - although reporting individual commercialisation successes, the views obtained on the efficacy and impact of SHIL were mixed and require further evaluation – we understand that SHIL is re-assessing its business model and this seems timely
  - Bioquarter is a new initiative but has enjoyed early, if relatively small scale endorsement of its attractiveness following a recent announcement of an inward investor taking space on the site.
- 8.16 Figure 8.3 provides a summary of issues associated with routes to impact through pre clinical and clinical trials in Scotland.

Figure 8-3: Routes to economic impact – clinical trials



- 8.17 In terms of future impact, there is some growth expected in trials opportunities for CROs in Scotland as a result of the NRS Permissions CC initiative.
- 8.18 Other potential for economic growth exists in replicating the inward investment achieved by the TMRC through the work of the SAHSC. However, this may be largely to the direct benefit of revenue to the research base and NHS rather than indigenous businesses. Other than CROs who may benefit from the procurement of services (for pre-clinical and other early stage trials), the other benefits to the Scottish economy of TMRC and SAHSC will rely on the commercialisation of IP from translational research by new or existing Scottish firms. Here the challenges are the same as face SE in supporting the commercialisation of university IP more generally. A number of consultees point to opportunities from the commercialisation of research into biomarkers.
- 8.19 Bioquarter offers an additional attractor for inward investment to complement the factors associated with research excellence and the Scottish healthcare system that proved attractive to Wyeth when joining the TMRC. Both here and elsewhere in Scotland, high quality employment space and a critical mass of translational research excellence, with its accompanying complement of research-trained staff and post-graduate students, all contribute to Scotland's attractiveness as a location for Life Science companies.
- 8.20 It is relatively straightforward to 'fit' activity in support of TCM to government policy and SE strategy: it is relatively straightforward to develop the market failure rationale for support. The key uncertainty is the time to realising maximum impact of the existing interventions, notably the TMRC, SAHSC and Bioquarter.

- 8.21 The efforts to attract additional trials to Scotland can if successful bring short term economic benefit, albeit possibly on a limited scale. The implementation of plans for Bioquarter has already attracted inward investment (the proposed location to Bioquarter of TPP Global Development) and the initiatives involving the academic research base aim to attract further investment in TCM capability and activity to the Scottish university base. These and other attractors of academic research and commercial inward investment will operate over the medium to long term (e.g. the economic impact appraisal for Bioquarter suggests it will be c. 25 years before the vision is delivered in full). Indigenous business growth as a consequence of the commercialisation of IP is an ongoing process and one that inherently has an uncertain rate of build. SE's own intelligence available presently from its account management and high growth business start-up support functions may offer one route to obtaining empirical evidence on the likely economic 'build rate' at least over the next c. 5 years.

### ***Competitive positioning transformed to economic growth***

- 8.22 There is a fairly widespread endorsement of the view that Scotland is well positioned internationally with respect to the competitive position of its TCM-related assets – its research and clinical excellence; the characteristics of its healthcare system and its cadre of CROs. The point is also made that the TMRC is a validation of Scotland's attractiveness to big pharma. Overall, however, we consider that it is harder to sustain an assertion that Scotland has (or can rely upon) a 'unique' selling point in what is a highly competitive UK and international market.
- 8.23 Two points need to be made however: (i) there is a widespread recognition that Scotland's position with respect to commercialisation achievements lags behind its research and clinical excellence; and (ii) there is a strong sense that TMRC may not be meeting early expectations.
- 8.24 Commercialisation and replicating the inward investment of the type associated with TMRC are the key paths to transforming competitive position in research and clinical medicine into economic growth. Both these issues therefore require close attention by SE.
- 8.25 In this context, the 'jury is still out' over whether the SAHSC can transform Scotland's competitive assets in research and clinical excellence into economic growth. On commercialisation specifically, it is likely to be the 'standard' products in SE's toolkit to support commercialisation and innovation that would be more directly useful than the current set of TCM-related interventions by themselves, especially over the medium term.

### **Enhancing the TCM-related business environment - role and next steps for SE**

- 8.26 From all the suggestions made by consultees, we would advise that the following issues be given priority attention by SE:
- a re-assessment of how much value-adding collaboration is ongoing within all the current interventions that has an influence and beneficial impact *specifically* on indigenous businesses

- the nature and feasibility of enhancing further the exchange of knowledge and people between the research-base and indigenous businesses e.g. through Knowledge Transfer Partnerships, internship programmes and other means attractive to individual businesses
- on marketing of the TCM interventions, to re-assess the efficacy of marketing efforts towards pharma companies internationally (not least in our view due to the ongoing changes in the structure of this international industry, including closure of R&D facilities and outsourcing), towards investors (inward investors and risk capital investors) and towards indigenous companies.

- 8.27 From the evidence gained from the study more generally, we conclude that there is a need to articulate much more clearly towards the business-base in Scotland the relevance to them of the TCM initiatives that are already being supported and to monitor and evaluate the actual benefits to business in Scotland that are delivered over time. Notwithstanding the relative immaturity of some of the interventions, there is a sense of their dislocation from Scotland's business base which may presently derive more benefit from access to SE's 'standard products'. We also sense that there remains work to be done to encourage industry leadership and action in the implementation of business-relevant initiatives, working pro-actively and collaboratively, rather than SE 'owning' all the challenges.
- 8.28 Raised awareness within the relevant business-base in Scotland of the nature and potential business value of the current TCM-related interventions is a preparatory step towards encouraging greater industry leadership in implementing strategies to enhance the TCM-landscape in Scotland for business and economic development purposes.
- 8.29 In addition to the catalytic and facilitation roles SE should continue to play in supporting the development of the TCM-related business environment, a key role is to deploy effectively its 'standard' toolkit of support to ensure that translational research (including especially biomarker research where informants point to good growth opportunities) conducted now and in the future through initiatives such as TMRC and SAHSC is commercialised to the benefit of the Scottish business-base and economy. Growth in demand for and take-up of for example its investment, business start-up and business growth-related products for TCM-derived business opportunities will be an important indicator that upstream investment in the research-base is bearing other economic development benefits.
- 8.30 With uncertainty over the time to realising optimum impact of the existing interventions, it will be important for SE to maintain a good level of knowledge of what is in the 'pipeline' of commercial leads and prospects associated with translational activities. Effort should be directed towards ensuring a portfolio of outputs that will bring short, medium and longer term benefits.
- 8.31 There also remains a key role for SDI in developing prospects for inward investment, a role that is crucial to the success of SAHSC and Bioquarter. Also, it is relevant to note the importance of exporting to many of the businesses consulted during this study.
- 8.32 For both CROs and diagnostics companies in Scotland, we would suggest that a key role for SE is to provide the kind of ongoing support delivered by its account managers and to ensure

that the nature and relevance of the existing TCM-related interventions are communicated effectively to all relevant businesses in Scotland. Developing the ‘message’ on TCM for business ‘clients’ and gauging their response will provide SE with one ‘acid’ test of the business relevance of the current TCM-related initiatives it is supporting.

- 8.33 Finally, preparatory to future evaluation of the various TCM-related interventions, we advise that SE re-assesses the adequacy of its baseline evidence on business and economic performance in this area.

### **Significance for equity and equality agendas**

- 8.34 From our high level review of the existing interventions and from the overarching objectives of the support for translational and clinical medicine, we find no indications of disadvantage to any group in Scotland whether defined by gender, ethnicity or disability. The existing interventions in support of TCM bring together public health and economic objectives in a complementary way and through attraction of and support for clinical trials in Scotland it is likely that patients benefiting from participation in trials may be drawn from across Scotland.

## Annex A: Recommendations for a monitoring and evaluation framework for existing TCM-related interventions

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- A.1 For SE in the context of its current strategy, the economic impact from an initiative such as TMRC comes from the initial investment made and then the sustained presence in Scotland by an inward investor (pharma company) - employing staff in Scotland and purchasing goods and services from a supply chain in Scotland. Investment from this same source in R&D within the Scottish research-base of course also creates and/or sustains employment, but not directly in businesses in Scotland.
- A.2 For this and for all the other TCM-related interventions reviewed in this Section, we offer our ‘from first principles’ assessment of routes to potential economic outcomes and impact. We restrict this specifically to routes to growth through the business base (as distinct from safeguarding or creating employment in the university sector, through university procurement, recycling of revenue to the NHS etc.):
- the translational research activity leads to the commissioning of work from CROs based in Scotland (e.g. for pre-clinical studies or early stage clinical trials)
  - the research leads to Intellectual Property (IP) which is exploited successfully by the inward investor (by the pharma company) directly, which leads to a sustained and perhaps growing business presence in Scotland
  - the research leads to the development of IP which is licensed to Scottish companies which go on to exploit it successfully and grow their business in Scotland as a result
  - the research leads to the development of IP that is exploited through the establishment of spin-out companies which go on to exploit it successfully and grow a business in Scotland as a result.
- A.3 All four routes depend on the scale, quality and timing of the commercialisation of the translational research output. Issues of take-up and efficacy of SE’s generic processes and ‘products’ in support of commercialisation are therefore relevant here. The latter two routes also depend on the ownership of the IP and the interests and policies on exploitation of the pharma company partner (on its corporate model of innovation). It is important to note that in business terms, the R&D is one *input* to business development.
- A.4 We now comment on the routes to economic impact for each of the current interventions in turn.



## TMRC

### **Routes to economic impact**

A.5 In addition to the (important) potential introduction to the Scottish labour market of research trained Life Scientists and to health outcomes in Scotland, the routes to potential economic outcomes and impact based on a ‘from first principles’ assessment of the TMRC, in terms relevant now to SE, are as follows:

- the translational research activity leads to the commissioning of work from CROs based in Scotland (e.g. for pre-clinical studies or early stage clinical trials)
- the research leads to Intellectual Property (IP) which is exploited successfully by the inward investor (by the pharma company) directly, which leads to a sustained and perhaps growing business presence in Scotland
- the research leads to the development of IP which is licensed to Scottish companies who go on to exploit it successfully and grow their business in Scotland as a result
- the research leads to the development of IP that is exploited through the establishment of spin-out companies who go on to exploit it successfully and grow a business in Scotland as a result.

A.6 All four routes depend on the scale, quality and timing of the commercialisation of the translational research output. Issues of take-up and efficacy of SE’s generic processes and ‘products’ in support of commercialisation are therefore relevant here. The latter two routes also depend on the ownership of the IP, and the interests and policies on exploitation of the pharma company partner (on its corporate model of innovation). It is important to note that in business terms, the R&D is one *input* to business development.

Table A-1: Measures for monitoring and evaluating existing TCM interventions - TMRC

MEASURE	METHOD AND SOURCE	RESPONSIBILITY	FREQUENCY	NOTES
<b>INPUTS:</b>				
<b>Income</b> - for R&D and translational activities	Desk based review of records kept by TMRC	TMRC	Monitored every 6 months	- a pointer to sustainability of the R&D capability and activity
<b>Investment</b> – in capability/facilities	Desk based review of records kept by TMRC	TMRC	Monitored every 6 months	- a pointer to sustainability of the R&D capability and activity
<b>ACTIVITIES:</b>				
<b>engagement with CROs and other relevant businesses in Scotland</b> - to raise awareness of TMRC and of the business opportunities it can offer	Desk based review of records kept by TMRC	TMRC	Monitored every 6 months	The company contacts will be useful for evaluation

MEASURE	METHOD AND SOURCE	RESPONSIBILITY	FREQUENCY	NOTES
<b>engagement with potential risk investors</b> - to raise awareness of TMRC and of the opportunities for commercialisation it can offer	Records kept by TMRC	TMRC	Monitored every 6 months	
<b>OUTPUTS:</b>				
<b>Commercialisation pipeline –</b> <ul style="list-style-type: none"> <li>number of inventions disclosed and supported</li> <li>number/value of proof of principle/feasibility studies being advanced</li> <li>number/value of market studies being advanced</li> <li>number/value of development studies/trials being commissioned – including from suppliers in Scotland</li> <li>patent applications filed – and granted</li> </ul>	Desk based review of records kept by TMRC	TMRC	Monitored every 6 months	<ul style="list-style-type: none"> <li>- useful lead indicators of future commercialisation outcomes and impact.</li> <li>There would also be merit in tracking the demand from TMRC for SE's standard 'products' related to commercialisation support.</li> </ul>
<b>OUTCOMES/ IMPACT:</b>				
<b>value to Scottish businesses</b> - of work undertaken with/for TMRC	Primary research with intended business beneficiaries	Public sector funders in Scotland to undertake or commission an evaluation	Evaluated every 2 years	- captured as business metrics (turnover, employment) that can be translated into gross GVA
<b>Investment income</b> – risk finance directly to TMRC or to indigenous companies to whom TMRC's IP is transferred	Desk based review of records kept by TMRC plus primary research with beneficiaries if relevant	Public sector funders in Scotland to undertake or commission an evaluation	Evaluated every 2 years	- could be regarded as a financial 'input' but it is a market test of value.
<b>GVA</b> - impact of inward investment (gross and net)	Primary research with any relevant inward investors	Public sector funders in Scotland to undertake or commission an evaluation	Evaluated every 2 years	- from investors/ licensees locating to Scotland in order to exploit capabilities of TMRC and its IP
<b>GVA</b> - impact on growth of indigenous businesses (gross)	Primary research with any intended business	Public sector funders in Scotland to undertake or commission an	Evaluated every 2 years	- from work done for and/or IP transferred from TMRC

MEASURE	METHOD AND SOURCE	RESPONSIBILITY	FREQUENCY	NOTES
and net)	beneficiaries	evaluation		

## NRS Permissions Co-ordinating Centre

### *Routes to economic impact*

A.7 In addition to any contributions to health outcomes in Scotland, the routes to potential economic outcomes and impact based on a ‘from first principles’ assessment of the NRS Permissions CC are as follows:

- as a result of the efforts of the NRS Permissions CC, more trials are conducted in Scotland by companies with no base in Scotland – this provides an additional revenue stream to the NHS
- more trials are conducted in Scotland which are undertaken by CROs with a base in Scotland – in addition to NHS revenue, the CROs in Scotland benefit from increased business
- because of the improved efficiency brought about by the NRS Permissions CC, those CROs presently with a base in Scotland find it attractive to sustain their presence here
- given that more trials are conducted in Scotland, CROs with no current presence here, decide to locate a business unit in Scotland
- the efficiency of the processes co-ordinated by NRS Permissions CC adds to the attractiveness of Scotland for inward investment in translational research by global pharma.

### *Proposed measures*

Table A-2: Measures for monitoring and evaluating existing TCM interventions – NRS Permissions Co-ordinating Centre

MEASURE	METHOD AND SOURCE	RESPONSIBILITY	FREQUENCY	NOTES
<b>INPUTS<sup>31</sup>:</b>				
<b>Expert staff and specialist facilities</b> – capability and capacity of NHS Health Boards that is willing and able to engage in the conduct of trials in Scotland	Desk based review of records on responses to applications held by NRS PCC	NRS PCC	Monitored every 6 months	- relevant to assessing extent to which capability/capacity issues in the NHS are a barrier to the growth of trials activity
<b>ACTIVITIES:</b>				

<sup>31</sup> Revenue to NRS PCC and the Health Boards is an appropriate metric for these bodies but we understand that SE is concerned with measures that link more directly to business activity.

MEASURE	METHOD AND SOURCE	RESPONSIBILITY	FREQUENCY	NOTES
<b>engagement with pharma and CROs</b> – in order to market Scotland as a place to undertake trials	Desk based review of records of contacts made held by NRS PCC	NRS PCC – supported in delivery of marketing effort by SE	Monitored every 6 months	- could measure e.g. the distribution of marketing material, awareness raising events; individual company briefings etc. as outputs from this activity
<b>inward investment targets</b> - assessing CROs from outside Scotland who undertake repeated trials here as inward investment 'targets'	Desk based review of records of contacts made held by NRS PCC and by SE/SDI	NRS PCC – supported in assessment by SE/SDI	Monitored every 12 months	- important that any actual in-movers supported to locate in Scotland are not simply displacing CROs already in Scotland
<b>OUTPUTS:</b>				
<b>number and scale of trials applications processed</b> – also with a measure of 'efficiency'	Desk based review of records held by NRS PCC	NRS PCC	Monitored every 6 months	
<b>number of approvals secured</b> – also with a measure of 'efficiency'	Desk based review of records held by NRS PCC	NRS PCC	Monitored every 6 months	
<b>OUTCOMES/IMPACT:</b>				
<b>number and scale of trials conducted</b> – including measure of those conducted by indigenous CROs	Desk based review of records held by NRS PCC	NRS PCC	Monitored every 6 months	
<b>'satisfaction' of pharma and CROs with services provided</b>	Desk based review of records held by NRS PCC on client feedback plus primary research with the companies	NRS PCC	Evaluated annually	
<b>GVA contribution</b> - by indigenous CROs whose trials have been assisted by NRS PCC	Primary research with CRO beneficiaries to supplement NRS PCC records	Public sector funders in Scotland to undertake or commission an evaluation	Evaluated every 2 years	
<b>GVA contribution</b> – companies engaging in clinical trials from outside Scotland making an inward investment here	Primary research with any relevant investors	Public sector funders in Scotland to undertake or commission an evaluation	Evaluated every 2 years	- may be attributable in whole or in part to factors other than NRS PCC

## SAHSC

### **Routes to economic impact**

A.8 In addition to the (important) potential introduction to the Scottish labour market of research trained Life Scientists and to health outcomes in Scotland, the routes to potential economic outcomes and impact based on a ‘from first principles’ assessment of the SAHSC, in terms relevant now to SE, are as follows:

- the translational research activity attracted by the SAHSC leads to the commissioning of work from CROs based in Scotland (e.g. for pre-clinical and other early stage trials)
- the translational research activity that is funded by an inward investor (by a pharma company) is accompanied by the investor establishing a project team/ business unit in Scotland
- the translational research leads to IP which is exploited successfully by the inward investor (by the pharma company) directly, leading to sustained and perhaps a growing business presence in Scotland
- the translational research leads to the development of IP which is licensed to Scottish companies which go on to exploit it successfully, and grow their business in Scotland as a result
- the translational research leads to the development of IP which is exploited through the establishment of spin-out companies which go on to exploit it successfully, and grow a business in Scotland as a result.

A.9 At the level of investigation into the SAHSC undertaken in the present study, the routes to economic impact, especially ones involving businesses operating in Scotland, appear to be similar to those envisaged for TMRC. However different the governance arrangements may be, it will be important for SE to establish whether the prospects for the kind of economic impact it wishes to see delivered through SAHSC is likely to be any different in terms of route and/or scale to that in prospect from TMRC.

### **Proposed measures**

Table A-3: Measures for monitoring and evaluating existing TCM interventions – Scottish Academic Health Science Collaboration

MEASURE	METHOD AND SOURCE	RESPONSIBILITY	FREQUENCY	NOTES
<b>INPUTS:</b>				
<b>Income</b> – for collaborative R&D and translational activities	Desk based review of records kept by SAHSC	SAHSC	Monitored every 6 months	- a pointer to sustainability of the R&D capability and activity
<b>Investment</b> – in capability/facilities	Desk based review of records kept by SAHSC	SAHSC	Monitored every 6 months	- a pointer to sustainability of the R&D capability and

MEASURE	METHOD AND SOURCE	RESPONSIBILITY	FREQUENCY	NOTES
				activity
<b>ACTIVITIES:</b>				
<b>engagement with CROs and other relevant businesses in Scotland</b> - to raise awareness of SAHSC and of the business opportunities associated with its pan-Scotland programmes	Desk based review of records kept by SAHSC	SAHSC	Monitored every 6 months	The company contacts will be useful for evaluation
<b>engagement with potential risk investors</b> - to raise awareness of SAHSC and of the opportunities for commercialisation associated with its pan-Scotland programmes	Desk based review of records kept by SAHSC	SAHSC	Monitored every 6 months	
<b>engagement with other potential inward investors</b> - to raise awareness of opportunities for collaboration associated with its pan-Scotland programmes	Desk based review of records kept by SAHSC	SAHSC with SE/SDI	Monitored every 6 months	
<b>OUTPUTS:</b>				
<b>Documented assessments of leads/prospects</b> - for pan-Scotland initiatives funded at least in part by business	Documentation prepared by SAHSC	SAHSC supported by SE/SDI	Monitored every 6 months	- useful lead indicator of eventual outcomes and impact
<b>Commercialisation pipeline associated with SAHSC's programmes of R&amp;D and related translational activity –</b> <ul style="list-style-type: none"> <li>number of inventions disclosed and supported</li> <li>number/value of proof of principle/feasibility studies being advanced</li> <li>number/value of market studies being</li> </ul>	Desk based review of records kept by SAHSC	SAHSC	Monitored every 6 months	- useful lead indicators of future commercialisation outcomes and impact.  There would also be merit in tracking the demand arising from SAHSC activity and outputs for SE's standard 'products' related to commercialisation support.

MEASURE	METHOD AND SOURCE	RESPONSIBILITY	FREQUENCY	NOTES
<p>advanced</p> <ul style="list-style-type: none"> <li>number/value of development studies/trials being commissioned – including from suppliers in Scotland</li> <li>patent applications filed – and granted</li> </ul>				
<b>OUTCOMES/ IMPACT</b>				
<b>value to Scottish businesses</b> - of work undertaken with/for SAHSC's programmes of R&D and related translational activity	Primary research with intended business beneficiaries	Public sector funders in Scotland to undertake or commission an evaluation	Evaluated every 3 years	- captured as business metrics (turnover, employment) that can be translated into gross GVA
<b>Investment income</b> – risk finance directly to SAHSC programmes or to indigenous companies to whom IP from SAHSC's programmes is transferred	Desk based review of records kept by SAHSC plus primary research with beneficiaries if relevant	Public sector funders in Scotland to undertake or commission an evaluation	Evaluated every 3 years	- could be regarded as a financial 'input' but it is a market test of value.
<b>GVA</b> - impact of inward investment attracted by SAHSC (gross and net)	Primary research with any relevant inward investors	Public sector funders in Scotland to undertake or commission an evaluation	Evaluated every 3 years	- from investors/ licensees locating to Scotland in order to engage with SAHSC's programmes and/or exploit the IP they generate
<b>GVA</b> - impact on growth of indigenous businesses (gross and net)	Primary research with any intended business beneficiaries	Public sector funders in Scotland to undertake or commission an evaluation	Evaluated every 3 years	- from work done for and/or exploiting IP transferred from programmes established by SAHSC

## SHIL

### *Routes to economic impact*

- A.10 In addition to any contributions to health outcomes in Scotland, the routes to potential economic outcomes and impact based on a 'from first principles' assessment of SHIL are as follows:



- licensing of IP based on NHS inventions to companies outside Scotland who pay royalties to SHIL/NHS Health Boards which is then 're-cycled' into the Scottish economy
- licensing of IP to companies based in Scotland which go on to exploit it successfully, and grow their business in Scotland as a result
- exploitation of IP through the establishment of spin-out companies which go on to exploit it successfully, and grow a business in Scotland as a result.

A.11 Given the term over which SHIL has been in receipt of public sector support, it is almost inevitable that questions concerning exit strategies for certain public sector funders will be raised. It is unlikely that market failures associated with proving-up and taking forward to market NHS inventions will have been 'cured' by now and it seems clear from SHIL's 2009 Annual Report that it is far from being self-sustaining on the back of commercial revenue generation.

A.12 It would appear that SHIL is operating at a position that is highly relevant to SE in the short to medium term, albeit working with only a sub-set of commercialisation opportunities i.e. not principally with those that may emerge from translational research. For this reason, there should be a strong interest in SE in determining the scale of net added value it is achieving from empirical evidence and in assessing the likely sustainability and scope for up-scaling of its operation and outputs.

### Proposed measures

Table A-4: Measures for monitoring and evaluating existing TCM interventions – SHIL

MEASURE	METHOD AND SOURCE	RESPONSIBILITY	FREQUENCY	NOTES
<b>INPUTS:</b>				
<b>support from NHS Health Board management – financial and other strategic inputs</b>	Desk based review of records kept by SHIL	SHIL	Monitored every 12 months	
<b>Inventions disclosed and supported</b>	Desk based review of records kept by SHIL	SHIL	Monitored every 6 months	- these disclosures are key 'inputs' into SHIL's activities/processes
<b>ACTIVITIES:</b>				
<b>engagement with relevant businesses in Scotland - to raise awareness of SHIL and of the business opportunities it offers</b>	Desk based review of records kept by SHIL	SHIL	Monitored every 6 months	The company contacts will be useful for evaluation
<b>engagement with potential risk investors - to raise awareness of SHIL and of the opportunities for</b>	Desk based review of records kept by SHIL	SHIL	Monitored every 6 months	

MEASURE	METHOD AND SOURCE	RESPONSIBILITY	FREQUENCY	NOTES
commercialisation it offers				
<b>OUTPUTS:</b>				
<b>Commercialisation pipeline:</b> <ul style="list-style-type: none"> <li>number/value of proof of principle/ feasibility studies being advanced</li> <li>number/value of market studies being advanced</li> <li>number/value of development studies/trials being commissioned – including from suppliers in Scotland</li> <li>patent applications filed – and granted</li> </ul>	Desk based review of records kept by SHIL	SHIL	Monitored every 6 months	There would also be merit in tracking the demand from SHIL's activities and outputs for SE's standard 'products' related to commercialisation support.
<b>OUTCOMES/ IMPACT:</b>				
<b>Investment</b> - scale of risk finance secured for projects	Desk based review of records kept by SHIL plus primary research with other beneficiaries if relevant	SHIL	Monitored every 12 months	
<b>Licensing</b> - number of licenses concluded plus revenue stream generated (including from sources in Scotland)	Desk based review of records kept by SHIL	SHIL	Monitored every 12 months	
<b>New firm formation</b> - number of new firms established in Scotland ( with 'quality' measures on sustainability and growth)	Desk based review of records kept by SHIL	SHIL	Monitored every 12 months	
<b>GVA</b> - impact on indigenous businesses supported by SHIL (gross and net)	Primary research with intended beneficiaries	Public sector funders in Scotland to undertake or commission an evaluation	Evaluated every 3 years	

## Bioquarter

### Routes to economic impact

A.13 In addition to contributions to health outcomes in Scotland, the envisaged routes to economic impact associated with Edinburgh Bioquarter appear to be as follows:

- the location and its associated ‘assets’ in the University and NHS (including ‘talented’ people and the opportunities to take-up attractive licensing opportunities) act as attractors to inward investors who establish and sustain business units on site<sup>32</sup>
- the ‘assets’ in the University and the NHS are transferred/commercialised to a greater degree than before as a result of the commercial activity and associated support available on site, and the exploitation of this IP contributes to the growth of new and/or existing businesses in Scotland
- businesses (inward investors or indigenous firms) locating to Bioquarter develop new or enhanced collaborative ventures with the co-located University and/or NHS ‘assets’ which in turn lead to new opportunities for business growth.

A.14 There will of course be short term benefits from the construction activity on site.

### Proposed measures

Table A-5: Measures for monitoring and evaluating existing TCM interventions – Bioquarter

MEASURE	METHOD AND SOURCE	RESPONSIBILITY	FREQUENCY	NOTES
<b>INPUTS:</b>				
<b>Income</b> – for collaborative R&D and translational activities	Desk based review of records kept by Bioquarter	Bioquarter	Monitored every 6 months	- a pointer to sustainability of the R&D capability and activity
<b>Investment</b> – in capability/facilities	Desk based review of records kept by Bioquarter	Bioquarter	Monitored every 6 months	- a pointer to sustainability of the R&D capability and activity
<b>ACTIVITIES:</b>				
<b>engagement with CROs and other relevant businesses in Scotland</b> - to raise awareness of the business opportunities	Desk based review of records kept by Bioquarter	Bioquarter	Monitored every 6 months	The company contacts will be useful for evaluation
<b>engagement with</b>	Desk based review	Bioquarter	Monitored every 6	

<sup>32</sup> During our primary research, informants associated with support for international trade commented on the prospects for inward investment to Scotland associated with TCM. It appears that prospects of attracting companies in diagnostics to Scotland are not highly rated. These consultees reason that the healthcare reimbursement model which operates in the US makes it more attractive as a location for investment.

MEASURE	METHOD AND SOURCE	RESPONSIBILITY	FREQUENCY	NOTES
<b>potential risk investors</b> - to raise awareness of the opportunities for commercialisation	of records kept by Bioquarter		months	
<b>engagement with other potential inward investors</b> - to raise awareness of opportunities for collaboration	Desk based review of records kept by Bioquarter	Bioquarter with SE/SDI	Monitored every 6 months	
<b>OUTPUTS:</b>				
<b>Commercialisation pipeline associated with of R&amp;D and related translational activity –</b> <ul style="list-style-type: none"> <li>number of inventions disclosed and supported</li> <li>number/value of proof of principle/ feasibility studies being advanced</li> <li>number/value of market studies being advanced</li> <li>number/value of development studies/trials being commissioned – including from suppliers in Scotland</li> <li>patent applications filed – and granted</li> </ul>	Desk based review of records kept by Bioquarter	Bioquarter	Monitored every 6 months	There would also be merit in tracking the demand from Bioquarter related activities and outputs for SE's standard 'products' related to commercialisation support and support for attracting inward investment.
<b>OUTCOMES/ IMPACT:</b>				
<b>Value to Scottish businesses</b> - of programmes of R&D and related translational activity	Primary research with intended business beneficiaries	Public sector funders in Scotland to undertake or commission an evaluation	Evaluated every 3 years	- captured as business metrics (turnover, employment) that can be translated into gross GVA
Inward investment attracted	Primary research with business beneficiaries	Public sector funders in Scotland to undertake or commission an evaluation	Evaluated every 3 years	World class companies attracted to Bioquarter, including at least 1 major pharma company
Equity investment attracted	Primary research with business	Public sector funders in Scotland to undertake or	Evaluated every 3 years	

MEASURE	METHOD AND SOURCE	RESPONSIBILITY	FREQUENCY	NOTES
	beneficiaries	commission an evaluation		
Companies incubated successfully	Primary research with intended beneficiaries	Public sector funders in Scotland to undertake or commission an evaluation in association with Bioincubator manager	Evaluated every 3 years	With quality measures for growth and sustainability
GVA - impact on businesses in Scotland	Primary research with intended beneficiaries	Public sector funders in Scotland to undertake or commission an evaluation	Evaluated every 3 years	Including through creating net additional employment

## **Annex B: List of consultees**

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B.1 The list below identifies company consultees:

- Dr Deborah O'Neill, NovaBiotics
- Dr Brian Bathgate, Charles River
- Dr Janet Halliday, Controlled Therapeutics
- Dr David Hill, Schering-Plough
- Dr Tom Shepherd, CXR Bioscience
- Dr Colin Morgan, jnj
- Dr Paul McBarron, Cyclacel
- David Scott, Tepnel
- Dr David Galloway, Cytosystems
- Chris Hillier, Systemic.

B.2 Three other companies were not pursued after repeated phone/ voicemail and email requests.

B.3 Other consultees are:

- Professor Irene Leigh, University of Dundee
- Tony Wells, NHS Tayside
- Professor Jonathan Seckl, University of Edinburgh
- Professor Sir John Savill, University of Edinburgh and Chief Scientist, Scottish Government Health Department
- Richard Carey, NHS Grampian
- Professor David Newby, University of Edinburgh
- Mr Barbour, NHS Lothian
- Professor Chris Packard, NHS Greater Glasgow & Clyde
- Professor David Barlow, University of Glasgow
- Ian Leslie and Neil Guthrie, SDI
- Rhona Allison, Scottish Enterprise.

B.4 One other academic contact was not pursued after repeated phone/ voicemail and email requests.

## **Annex C: Profiles of comparator TCM locations**

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C.1 This annex assesses public domain information on the nature and impact of TCM in other selected places internationally. The paper aims to highlight lessons which may be learned in terms of:

- articulation of competitive position
- routes to economic outcomes and impacts (and associated roles)
- identifying implied logic models
- interdependencies between interventions

C.2 The locations selected on the basis of client interest and our own desk research are:

- the Global Medical Excellence Cluster (GEM), UK
- the London area
- Singapore
- Pennsylvania, USA
- Sweden
  - domestic east and west coasts
  - trans-national Oresund Science Region with Denmark.

### **Headline messages emerging from the review**

C.3 A number of key factors can be discerned from this review:

- areas promote and build on existing reputation and capabilities created over extended periods of time, including:
  - the history and ‘pedigree’ of people and institutions – commonly classed as world-leading in their field).
  - presence of renowned anchor organisations within the area e.g. academia, medical research hospitals and presence of multi-national corporations
- emphasis on good governance structures for collaborative initiatives:
  - common use of cluster and/or Triple Helix concepts and implementation frameworks with support from universities, hospitals, industry and government, and in places trans-national in scope
  - but also giving close attention to networking and bottom-up approaches
- exploiting market potential facilitated by:



- existing commercial strengths in the area – entrepreneurs, investors and multi-national company engagement
- relevance and growth potential of research area to dynamic global markets
- realising future impacts enabled through integrated or ‘systems’ appreciation of contributions from:
  - financial capital (invested in infrastructure and enterprises)
  - from public and private sector sources, and from seed funds through to major FDI
  - human capital (labour pool, skills, and volunteers for clinical trials)
  - knowledge capital (research excellence and invention)
  - understanding and alignment of regional and national systems of innovations

C.4 However, in general there is rarely a well articulated ‘theory of change’ and associated ‘logic model’ made explicit in the public domain. There are lots of strategy documents and vision statements, and much promotional information, but much less readily available to investigate the links between strategy, its actual implementation and subsequent evaluation. The example of the Greater Philadelphia area may provide one ‘place’ where with greater resource the true longitudinal pattern of development and impact might be determined.

C.5 It is notable that in contrast now to Scotland, there remains a strong emphasis elsewhere on an integrated approach to economic development that uses ‘clusters’ and related organising frameworks.

## Global Medical Excellence Cluster (UK)

C.6 The *Global Medical Excellence Cluster* (GMEC) is a not-for-profit company formed in 2007 bringing together leading universities, companies and NHS trusts in the South East of England. The University of Cambridge, of Oxford, Imperial College London, King’s College London and University College London founded the GMEC in partnership with GlaxoSmithKline, GE Healthcare, Pfizer UK, the Maudsley Hospital and the Royal Marsden Hospital to create what is claimed to be the largest healthcare cluster in Europe. It is funded from public and private sources.

C.7 The aims of GMEC are articulated in terms of: (1) building capabilities to keep the UK globally competitive in biomedical research; (2) attracting inward investment; and (3) improving patient outcomes.

C.8 In terms of process, new research programme ideas and proposals are submitted by scientists from the founder and partner organisations for consideration by the GMEC Cluster Committee, which meets five or six times a year. Cluster Committee members may also initiate proposals in response to strategic needs.

- C.9 Typically, projects involve a core of investigators drawn from the founders and partners. GMEC funding is designed to facilitate and catalyse proposals. Investigators from organisations external to the cluster can be included in projects.
- C.10 Although there are parallels in process with TMRI/TMRC, the key distinction is the involvement of more than one Pharma Company, i.e. of firms that are otherwise competitors.

Table C-1 Summary of the logic model for the Global Medical Excellence Cluster (GMEC)

Step	Description	Measures reported	Comments
Rationale	GMEC's vision is to improve patient outcomes and achieve a globally competitive position in biomedical science and innovation. [1]		
Objectives	To keep the UK globally competitive in biomedical research and to attract inward investment, in order to develop the next generation of medical advances in the UK. [1]		
Inputs	Resources from: universities, NHS and private sector partners.	Since its inception, GMEC has built a portfolio of bioscience research initiatives with a strong focus on therapeutics as well as on capability development.	Strong multiple 'blue chip' industry collaboration.
Outputs	Current CMEC programmes providing research outputs are: <ul style="list-style-type: none"> <li>GMEC Transplantation Programme</li> <li>Integrative Mammalian Physiology and Pharmacology</li> <li>Centre for Imaging and Biomarkers</li> <li>Nanosensors to Rapidly Detect Antibiotic-Resistant Superbugs</li> <li>GMEC Drug Discovery Working Group</li> </ul>	Outputs include: <ul style="list-style-type: none"> <li>Conference &amp; published articles on "Biomarkers in Brain Disease"</li> <li>GMEC Genetics in Transplantation Workshop</li> <li>GMEC Integrative Mammalian Physiology and Pharmacology Meeting</li> </ul>	
Outcomes		Each programme brings together leading researchers from across the partner universities with agreed research objectives and plans.  GMEC has successfully fostered and supported projects in a variety of areas of biomedicine, including organ transplantation, biomarker infrastructure and nanotechnology.  No quantitative outcomes identified specifically for GMEC to date. Research outcomes tend to be attributable to individual groups or institutions.	Perhaps because it is too early but outcome and impact evidence attributable to the GMEC structure is not 'obvious' in the public domain.
Impacts		None identified specifically for the GMEC to date.	

### Key learning

- C.11 There is a clear implication that even significant centres or excellence in their own right see advantages in collaboration to create 'scale'. The collaboration is notable in involving a number of 'big pharma' companies, i.e. companies that compete in the market. It is difficult

from the information that is readily available on the web to determine just how the collaboration works in practice: as SE knows from its experience with TMRC, there is much that needs to be in place behind the public marketing to make these collaborations work effectively.

- C.12 The GMEC is built upon a clustering model of TCM capability and activity that has been adopted in the USA and other parts of Europe, with other examples emerging in Asia.

*Competitive positioning*

- C.13 The five GMEC founder universities; Cambridge, Oxford, Imperial College, Kings College, Oxford and University College are world-class, renowned medical and Life Science research-based institutions, with strong international ‘brands’, that historically have had a major impact on medical innovation and the healthcare industry. Their medical schools are in the top class of the latest (2008) UK RAE rating. The five founder universities are in the top 50 in the 2009 international ‘league table’ for Life Sciences and biomedicine, and two are in the top three<sup>33</sup>. (According to the same source, Edinburgh is ranked 34.)
- C.14 The level of ambition/aspiration is embedded in the full title of the initiative –‘Global Medical Excellence Cluster’. The key proposition is the conduct of TCM programmes using the existing capabilities, all from world-leading organisations. The cluster is also promoted as the largest aggregation of scientists in Life Sciences, biomedical sciences, translational research and clinical research in Europe.

*Routes to outcome and impact*

- C.15 Governance and oversight of GMEC is provided by the Board of the company, drawn from industry, healthcare and academia. Scientific strategy and oversight is the responsibility of the Cluster Committee, composed of senior staff from the industrial partners, the heads of the university Medical Schools and CEOs from the NHS trusts. The close involvement of industry in all these governance mechanisms is notable.
- C.16 A prime focus for GMEC has been to build capabilities from basic bioscience research through to specialist translational work in specific disease and therapeutic areas, including through the development and use of innovative enabling technologies. Research activities range from basic biology (physiology, inflammation) to specific disease related research (asthma) and innovative technology (imaging, nanotechnology). The component programmes/groups within of GMEC include:
- the GMEC Transplantation Programme
  - Integrative Mammalian Physiology and Pharmacology
  - Centre for Imaging and Biomarkers
  - GMEC Drug Discovery Working Group
  - Nanosensors to Rapidly Detect Antibiotic-Resistant Superbugs.

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<sup>33</sup> See: <http://www.timeshighereducation.co.uk/hybrid.asp?typeCode=423>

- C.17 The founders and partner organisations collaborate especially in these areas to deliver scientific, clinical and infrastructure projects whose target outcomes include creating jobs and attracting inward investment. The including of both scientific and technology research within GMEC is notable.
- C.18 As GMEC is a relatively new organisation (established in 2007), the outcomes and impact it achieves in quantifiable economic development terms (in terms of GVA contributions) are not documented so far in the public domain, as best we can determine, and in any event it is at an early stage. Also, as GMEC operates at a strategic level, attribution down track will prove ‘challenging’.

### References cited for GMEC

- [1] Global Medical Excellence Cluster – GMEC. (<http://www.gmecuk.com/>)

### London area

- C.19 It is interesting to look at TCM issues based on the London geography, notwithstanding the overlap with the location of GMEC collaborators. *BioLondon* (see: <http://www.biolondon.org.uk>) is an initiative established by the London Development Agency (LDA) to facilitate the generation of “world-class biotechnology businesses” from the capabilities located within London [1], i.e. it has a much tighter, more explicit focus on economic development objectives.
- C.20 Linked to the BioLondon web site are networks including as an example the London Regenerative Medicine Network (LRMN: see <http://www.lrmn.com>). Established in early 2005 by two leading players in the field of stem cells and regenerative medicine this pan London network claims to be “the largest and most successful network in the UK with a membership of over 3,500”. The Network is a ‘not for profit organisation’ funded mainly by a three year grant from the LDA. Additional sponsorship comes from the law firm Clifford Chance which has a strong Life Sciences practice and the costs of its meeting are met by funding from industry.

Table C-2 Summary of the logic model for London

Step	Description	Measures reported	Comments
Rationale	<p>The biotechnology sector has the potential to create wealth, jobs and improve quality of life. Since London is strong in all elements of the biotechnology supply chain, there has been rapid and sustained growth in the number of biotechnology companies in the last decade. [1]</p> <p>Three healthcare sub-sectors were selected as a core focus because [2]:</p> <ul style="list-style-type: none"> <li>• a significant existing commercial presence</li> <li>• relevance to dynamic and expanding global markets</li> <li>• growth potential</li> <li>• strength of the relevant research base</li> <li>• potential for economic development</li> </ul>		

Step	Description	Measures reported	Comments
	<p>activities to make a meaningful impact on business development</p> <ul style="list-style-type: none"> <li>• current or potential linkages with other important industries in the Region</li> <li>• current or potential linkages with other identified Life Sciences sub-sectors.</li> </ul>		
Objectives	<p>The objective of the Life Sciences support strategy is to "develop a commercial Life Sciences cluster around London's world class knowledge base". The aim of BioLondon is [1]:</p> <ul style="list-style-type: none"> <li>• to establish physical space for Life Sciences by creating incubators, science parks and other specialist facilities</li> <li>• to build the Life Sciences cluster by creating support systems, promoting the cluster's image, promoting inward investment and working with the NHS</li> <li>• to encourage company growth by supporting skills development within the sector</li> <li>• to bridge the finance gap by enabling access to early stage funding</li> </ul>	<p>BioLondon has developed a strategy focusing on three main sub-sectors [2]:</p> <ul style="list-style-type: none"> <li>• Therapeutics</li> <li>• Contract Research Organisations</li> <li>• Biomedical Engineering</li> </ul>	<p>Notable CROs that are mentioned specifically</p>
Inputs	<p>In addition to LDA support, the key 'inputs' BioLondon relies on are the existing industry and academic 'assets'</p>	<p>Overview of London Life Sciences [1,2]:</p> <ul style="list-style-type: none"> <li>• over 6000 people working in pharmaceuticals</li> <li>• a further 175,000 in the wider healthcare sector</li> <li>• 28 universities which conduct teaching and research in Life Sciences</li> <li>• 55 Hospitals, trusts and medical schools, inc 23 Research hospitals</li> <li>• c.135 Life Sciences companies, including large pharmaceuticals [3] <ul style="list-style-type: none"> <li>➢ 67x therapeutics firms</li> <li>➢ 22x CRO/CMOs</li> <li>➢ 12x suppliers and services</li> <li>➢ 4x bio/chemo-informatics</li> <li>➢ 10x diagnostics/theranostics</li> </ul> </li> <li>• in excess of \$1billion public research funding annually to London [4]</li> </ul> <p>London is home to 3 of the 5 UK Academic Health Science Campuses and 4 of the 6 specialist biomedical centres of the National Institute for Health Research; 17 of the MRC's units centres and institutes; and</p>	

Step	Description	Measures reported	Comments
		CRUK's London Research Institute. [4]	
Outputs	The BioLondon initiative has delivered infrastructural and business development outputs and outcomes	<p><b>Space:</b> LDA assisted in providing 60,000 sq ft of incubator and office space at [5]:</p> <ul style="list-style-type: none"> <li>Queen Mary University of London</li> <li>London Bioscience Innovation Centre</li> </ul> <p><b>Business Growth:</b></p> <ul style="list-style-type: none"> <li>biotechnology firms in London up 40% in 2 years to 90. [5]</li> <li>60% of clinical trials in Europe are carried out in the UK, the majority of them in London [4]</li> </ul> <p><b>Funding:</b></p> <ul style="list-style-type: none"> <li>the London Technology Fund (LTF) has made 20 investments in eight companies, totalling £23m [6]</li> <li>the LDA has invested £3.2m in four Proof of Concept funds since 2005. [5]</li> </ul> <p><b>Training:</b></p> <ul style="list-style-type: none"> <li>the LDA has supported UCL in two training initiatives. [5]</li> <li>39,000 Life Science students providing a large, highly trained talent pool. [4]</li> </ul>	It is notable that BioLondon reports in an integrated way on infrastructure, business growth and access to finance, and training issues.
Outcomes	BioLondon reports outcomes in terms of the drug discovery pipeline associated with indigenous organisations	<p>Healthcare research into drug discovery is dominated in the therapy areas of:</p> <ul style="list-style-type: none"> <li>Oncology (56 drugs)</li> <li>CNS/neurology (25)</li> <li>cardiovascular/metabolic (31)</li> </ul> <p>This accounts for 59% of the 200 drugs in the pipeline of London-based firms. [7]. The phase of research is [8]:</p> <ul style="list-style-type: none"> <li>93x pre-clinical (57% of total)</li> <li>31x Phase I (16%)</li> <li>43x Phase II (23%)</li> <li>16x Phase III (8%)</li> <li>3x NDA/BLA/MAA (1%)</li> </ul> <p>Examples of outcomes from recent News releases:</p> <ul style="list-style-type: none"> <li>Imperial College London: A gene is identified which regulates heartbeat [9]</li> <li>Kings College London:</li> </ul>	

Step	Description	Measures reported	Comments
		Development of a laser treatment to reverse the effects of age-related macular degeneration – the leading cause of blindness. [10]	
Impacts	Although the economic development rationale is clear, no economic impact evidence has been found in the public domain.	<p>The achievements established by the delivery of the Strategy and associated action plan are:</p> <ul style="list-style-type: none"> <li>• introduction of Bioscience key account managers</li> <li>• establishment of Global Medical Excellence Cluster (GMEC)</li> <li>• establishment of the ATCare Centre - a new Assistive Technology initiative to bridge gaps between the research carried out within universities, the NHS, SMEs and the market</li> <li>• formation of NHS Innovations London (NHSIL) in 2005</li> <li>• formation of London Genetics Limited - consortium of leading science and medical institutions to form a commercial company to facilitate partnerships between industry and world class academic and clinical centres of excellence in genetics and genomics-based research across London - first point of contact for anyone looking to conduct basic research, translational research or clinical studies in London</li> <li>• development of three Life Sciences incubators</li> </ul>	

### Key learning

- C.21 The main strength promoted by BioLondon is the presence of a large, world class bioscience and clinical knowledge base. London can claim some of the best universities for Life Sciences and biomedicine in the world, two of them ranked in the top 25: Imperial College London, University College London<sup>34</sup>. The London universities claim 20 Nobel Prize winners in Physiology and Medicine [11].

### Competitive positioning

- C.22 In addition to ‘excellence’, the BioLondon positioning is based on the advantages of a London location [2]:

<sup>34</sup> <sup>34</sup> See: <http://www.timeshighereducation.co.uk/hybrid.asp?typeCode=423>



- access to human resources (technical staff and clinical trials volunteers)
- transport access to national and international locations
- access to financial markets for investment and sales.

C.23 As the 2003 Strategy points out [2], there were growth constraints associated with:

- limited physical space for new and expanding Life Sciences companies
- ease of access to seedcorn and follow-on funding
- company-to-company collaboration
- access to Intellectual Property generated within hospitals

C.24 BioLondon “strives to promote and unite London's strengths to create an environment that delivers world-class biotechnology businesses”. [2]

“London is a world-class city with a world-class reputation for excellence in a myriad of areas.” [12]

C.25 The promotion of London’s medical Life Sciences cluster extend back at least a decade:

*"London seems...to be a unique case. It has a number of leading Universities and research hospitals and accounts for over one third of the publicly funded research in Britain and trains over one quarter of the country's graduates. There are more venture capitalists and specialist services than elsewhere in the UK, and London is home to the UK and EU medicines regulatory agencies (Medicines Control Agency, Medical Devices Agency and European Medicines Evaluation Agency). We therefore believe that London has a huge potential for biotechnology start ups that can benefit from its unique strengths."*

Source: Biotechnology Clusters, report of a team led by Lord Sainsbury, Minister for Science, 1999.

C.26 Delving deeper into the Life Sciences strategy for London it is interesting to note the following statements in the context of the present study:

*“A large number of these companies are involved in the research and development (R&D) of therapeutics for human healthcare applications. Contract Research Organisations (particularly those involved in clinical trials) and biomedical engineering companies are also important sub-sectors for London. London is very strong in R&D but has fewer companies operating in the later stages of the value chain.”*

Source: London Life Sciences strategy and action plan, 2003-2007.  
(<http://www.lda.gov.uk/upload/pdf/BioLondonStrategy.pdf>)

C.27 One focus area for this strategy was on Contract Research Organisations in order to “extend the value chain and support Therapeutics”. The same document reported that:

*“Over 50% of the companies are involved in the R&D of therapeutics, or drugs, for human healthcare applications. Contract Research Organisations (CROs), particularly those involved in clinical trials, and biomedical engineering companies are the next most dominant sub-sectors in London.”*

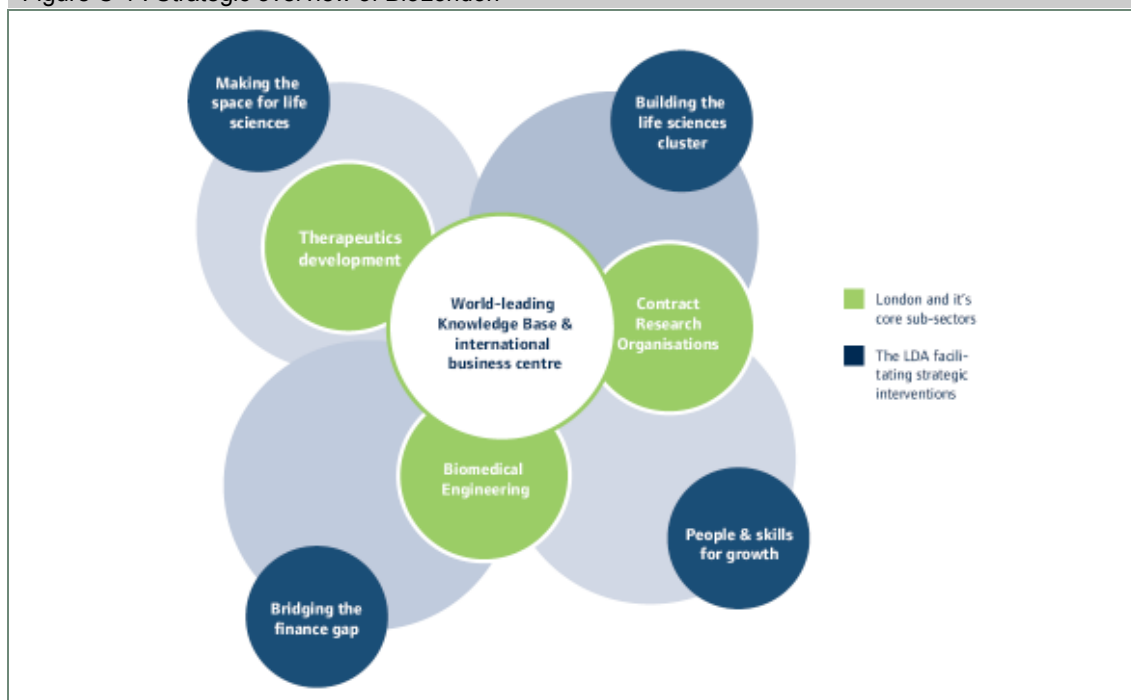
- C.28 Again extracting from the 2003-7 Strategy, the following reasons for the focus on CROs was provided:

*“The rationale for the selection of CROs – particularly clinical Contract Research Companies – as a niche area was based on London’s unique volunteer base, strong academic clinical research centres and strong company base. There is a critical mass of skills which are likely to migrate between these companies and the growth opportunities are significant given the global markets in this area. A significant feature of this selection was its potential to link with the therapeutics subsector to the mutual benefit of both areas. The business models of these companies also tend to require low levels of upfront investment, relying instead on retained profits, which balances the investment-based model that tends to dominate therapeutic development companies”*

#### *Routes to economic outcomes and impacts from London*

- C.29 BioLondon and the London Development Agency (LDA) promote expansion of the Life Sciences sector through support for physical infrastructure, human resources, networking and funding (direct and indirect), as illustrated in Figure C-1. The adherence to a ‘cluster’ concept is noted.

Figure C-1 : Strategic overview of BioLondon



Source: London Life Sciences Strategy and Action Plan (BioLondon, July 2003-2007)

#### *Additional information*

- C.30 In 2009, central government announced that three of the first five Academic Health Science Centres (AHSCs) in England will be based in London (Imperial College, King's Health Partners and UCL Partners). These centres are partnerships between academic medical research schools and NHS organisations, have been recognised as having the potential to compete globally with established centres such as those in the US, Canada, Singapore,

Sweden and The Netherlands. They are tasked with delivering world class research, education and patient care for the benefit of London and the public nationally and internationally.

- C.31 In its successful bid, Imperial College described its infrastructure to facilitate translation research in the following way:

*“The AHSC provides outstanding research infrastructure that is critical to meeting its goal of closing the gaps in translational medical research. We have four campuses at South Kensington, Hammersmith Hospital, St. Mary’s Hospital, and Charing Cross Hospital.*

*The Hammersmith campus has internationally renowned imaging sciences facilities, with six PET and eight MRI for humans, including the Imperial/GSK Clinical Imaging Centre, and the GE Healthcare Imanet.*

*The campus is home to the only Medical Research Council (MRC) Institute dedicated to translational medicine, the Clinical Sciences Centre (CSC), which has developed and implemented in vivo non-invasive imaging for rodent models, and we will shortly complete a large-mammal facility with PET and MRI imaging and interventional capabilities. The CSC also hosts genetic and genomic medicine platforms providing gene expression profiling, high-throughput genome-scale genotyping, DNA sequencing, data mining and warehousing. The Hammersmith houses an expanded vivarium for model organisms including world-leading rat genomics for complex traits and mouse genetics for transgenic knockout models, and GMP facilities for stem-cell intervention into stroke, heart, liver and pancreatic failure. This position will be strengthened through a new £100 million facility to incorporate cardiovascular sciences, translational medicine imaging (PET, MRI), a Wellcome Trust Clinical Research Facility and a MRC genomics centre.*

*We have established an AHSC Clinical Trials Unit, with the appointment of a senior Clinical Trials statistician, Professor Deborah Ashby. The unit supports trial design, implementation, database development and analysis, and integrates existing clinical triallists across the AHSC. It will seek formal NIHR accreditation in 2009. The AHSC also has six Facilities for Clinical Research embedded in or adjacent to clinical speciality areas for later stage clinical investigation and clinical trials, in Cardiovascular Medicine, Neonatology, Rheumatology, Infection, Hepatology and Paediatrics. A new Facility in Respiratory Infection will be built in 2009. These facilities are investigator-led, with core nurse and administrator support pro rata to research volume.*

*The AHSC provides infrastructure to facilitate translation from drug development through to commercialisation: the Drug Discovery Centre provides structural biology, medicinal chemistry and compound libraries to investigators; Imperial Innovations plc, a wholly owned subsidiary of Imperial College listed on London’s AIM market, supports commercialisation and licensing of the resulting therapies, devices and products. The AHSC will also build relationships with biotechnology companies, which typically have limited specialist medical input or clinical trial design capacity. It will perform ‘proof-of-principle’ trials, and is seeking companies with appropriate projects.”*

1. Source: <http://www.ourhhs.nhs.uk/wp-content/uploads/2009/06/imperial-college-ahsc-application-form-phase-1-for-publication.pdf>

- C.32 The bid document provides detailed information on how the AHSC will address two gaps in translational medicine (see: <http://www.ourhsc.nhs.uk/wp-content/uploads/2009/06/imperial-college-ahsc-application-form-phase-2-for-publication.pdf>):
- *the first gap*: from basic research through preclinical development to first in human trials
  - *the second 'gap'*: dissemination and application in healthcare delivery.
- C.33 Similar bid documents are in the public domain for AHSC's in Manchester, Kings College, Cambridge and UCL.

### References cited for London

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[11] London Biotechnology Network – The London BioGuide – Academia & Technology/Knowledge Transfer. (<http://www.londonbiotechnology.co.uk/London-BioGuide/Academia-technology-knowledge-transfer.aspx>)

[12] London Biotechnology Network – About us (<http://www.londonbiotechnology.co.uk/About-us.aspx>)

## Singapore

- C.34 A\*STaR is Singapore's lead government agency for assisting research in the biomedical sciences, located within the Biopolis 'hub'; and in the physical sciences and engineering within the Fusionopolis 'hub'. The Biomedical Research Council (BMRC) oversees the biomedical research agenda pursued by A\*STaR.
- C.35 Biopolis is located in close proximity to the National University of Singapore, the National University Hospital and Singapore science parks.

Table C-3 : Summary of the logic model for Singapore

Step	Description	Measures used	Comment
Rationale	Changing demographics and lifestyle is a worldwide trend that has an impact on the health of the population, bringing the challenges of rising healthcare costs and stretched medical resources to an ageing population in Singapore and other countries. Medical technology can play an enabling role in optimising the use of resources, improving quality of care, as well as containing costs to meet today's healthcare challenges. [2]		
Objectives	To spur growth in Singapore's key economic clusters by providing human, intellectual and industrial capital to our partners in industry and the healthcare sector. [1]  The Biomedical Sciences cluster was developed as one of the key pillars of Singapore's economy (alongside Electronics, Engineering and Chemicals). [1]		
Inputs	<ul style="list-style-type: none"> <li>human capital</li> <li>intellectual capital</li> <li>industrial capital [1]</li> </ul>	<ul style="list-style-type: none"> <li>in 2007, Gross expenditure on R&amp;D (GERD) reached S\$1.1billion (37% private and 63% public sector). [2]</li> </ul>	
Outputs	Infrastructural, people-related, manufacturing-related and TCM elements are promoted and reported as outputs (some more strictly outcomes).	<ul style="list-style-type: none"> <li>The flagship Biomedical hub Biopolis was opened in 2003. [2]</li> <li>Manufacturing output has increased around 3 times from S\$6.3 billion in 2000 to S\$19 billion in 2008. [2]</li> <li>Employment has more than doubled from 5,880 jobs in 2000 to 12,450 jobs in 2008 (4,169 within Pharmaceuticals and 8,281 in the MedTech sector). [2]</li> <li>Since 2001, A*STAR has awarded scholarships and fellowships in BMS to 524 young individuals, comprising 312</li> </ul>	

Step	Description	Measures used	Comment
		<p>National Science Scholarships, 28 MBBS-PhD scholarships, 143 A*STAR Graduate Scholarships and 41 International Fellowships. To date, more than 100 of these BMS scholars have completed their PhDs and returned to work at various A*STAR research institutes and units. [2]</p> <ul style="list-style-type: none"> <li>• Five Translational and Clinical Research (TCR) programmes adopted: <ul style="list-style-type: none"> <li>○ Cancer research</li> <li>○ Eye Disease</li> <li>○ Infectious Disease</li> <li>○ Metabolic Disease</li> <li>○ Neuroscience</li> </ul> </li> </ul>	
Outcomes	Industry investment outcomes are emphasised	<ul style="list-style-type: none"> <li>• Leading pharmaceutical, biotechnology and medical technology companies have invested in more than 50 commercial-scale manufacturing facilities in Singapore. [2]</li> <li>• Companies manufacturing in Singapore for the global market include half of the top 20 international pharmaceutical companies, e.g. Abbott, Genentech, GlaxoSmithKline (GSK), Merck, Novartis, Pfizer, Sanofi-Aventis, Schering-Plough, Wyeth and more than 25 medical technology companies including leaders such as Affymetrix, Siemens, Waters &amp; Becton-Dickinson. [2]</li> <li>• Many global leading medtech companies have set up R&amp;D facilities, such as Fluidigm, Hill-Rom, Qiagen, PerkinElmer &amp; 3M. [2]</li> <li>• A*STAR collaborate with CIMIT in the USA in S\$36m project. [2]</li> <li>• Private sector expenditure on BMS R&amp;D increased more than 4-fold, from \$88 million in 2001 to S\$427 million in 2007. [2]</li> <li>• BMRC research institutes have spun off several companies over the years, including Merlion Pharmaceuticals and Curiox. [2]</li> <li>• IP generated with the first “discovered-in-Singapore” drugs into clinical trials underway, and set to receive more than US\$600m in 2 licensing agreements for oncology drugs.</li> </ul> <p><b>There has been the development of a number of medtech innovations, these include [2]:</b></p> <ol style="list-style-type: none"> <li>1. Microfluidic device (“lab-on-a-chip”) to detect avian flu and other infectious diseases</li> <li>2. MicroKit, a portable diagnostic kit for fast and accurate detection of infectious diseases</li> <li>3. Diagnostic kit to detect the H1N1 virus.</li> <li>4. Tool to sequence the entire genome of the H1N1 virus.</li> <li>5. Home-based medical diagnosis system for</li> </ol>	

Step	Description	Measures used	Comment
		detecting/ monitoring selected illnesses and diseases.	
		6. Pyrosequencer innovations	
		7. Advanced therapeutic ingestible microcapsule with a camera for 'endoscopy' applications	
		8. Novel drug-loaded contact lens	
		9. The world's first photochromic contact lens	
Impacts	Economic impact and healthcare impacts are reported.	<ul style="list-style-type: none"> <li>The BioMedical Sciences (BMS) industry accounted for 4.1% of Singapore's GDP in 2008 [2]</li> <li>Value-added (VA) has shown an increase, from S\$3.8billion in 2000 to S\$10.6billion in 2008. [2]</li> <li>BMS provides some of the highest-paying jobs in the manufacturing sector. [2]</li> <li>Translational and Clinical Research (TCR) programme impacts over their first 3 years: <ul style="list-style-type: none"> <li>Early detection of 10x gastric cancers in patients from a cohort of 2,400, contributing to advancing knowledge</li> </ul> </li> <li>The Eye TCR has filed for 2x patents.</li> </ul>	

### **Other activities and 'assets'**

- C.36 There is a strong emphasis on in ward investment and on international partnering. The Center for Integrating Medicine & Innovative Technology (CIMIT) is a non-profit clinically-based consortium of Boston-area hospitals and engineering schools founded in 1998. It supports multidisciplinary translational research in medical device and clinical technology system applications. CIMIT is a globally recognised 'business model' for research collaborations, pipeline innovations and commercialisation within the medtech/ healthcare sector. (A similar model has been adopted in Manchester called MIMIT -Manchester: Integrating Medicine & Innovative Technology.)
- C.37 In 2009, A\*STaR signed an MoU with CIMIT for collaborative activities from 2010. Within this collaboration, engineers, clinicians and scientists in Singapore will be able to work with peers in Boston to develop engineering solutions that have clinical and market relevance. [2]
- C.38 'Biologics' is the fastest-growing segments of the pharmaceutical/biotech industry, which involves complex manufacturing processes dealing with living biological systems. A\*STAR's Bioprocessing Technology Institute (BTI) has the aim of establishing the necessary capabilities and expertise to attract biologics investment. In 2003, BTI's Biopharmaceutical Manufacturing Technology Centre was spun off as a company called A-Bio which attracted major contracts from GSK and Novo Nordisk, and has since secured six major biologics investments over the last 3 years, totalling more than S\$2 billion - from Genentech, Lonza, GSK, Novartis and Baxter. These are considered to have the potential to create 1,300 new jobs. [2]



- C.39 Singapore has also been highly successful in attracting corporate R&D facilities, with more than 50 companies carrying out R&D including in drug discovery and medical technology. Private sector expenditure on biomedical science R&D increased more than 4-fold, from \$88 million in 2001 to S\$427 million in 2007. [2]
- C.40 On Infrastructure, Biopolis serves as a research campus which co-locates both public and private sector R&D labs with more than 20 companies. Biopolis is now complemented by Fusionopolis (established in 2008) for the physical sciences and engineering. [2]
- C.41 Singapore is currently establishing Academic Medical Centres (AMCs) where basic research scientists and clinical researchers work together to strengthen translational and clinical research (TCR). The AMC is seen as providing the platform to translate more effectively and efficiently discoveries from the laboratory into new treatments and applications that benefit patients. [2]
- C.42 To support clinical trials, the Investigational Medicine Units (IMUs) and the Singapore Clinical Research Institute (SCRI) play a critical role in building up capabilities for early stage (Phase 1 to 2a) at IMUs, and late stage (Phase 2b to 3) at the SCRI. [2]
- C.43 There is a strong interest in attracting ‘First-in-Man’ and Phase 1 clinical trials to Singapore through pharmaceutical multi-nationals such as Abbott and AstraZeneca. Companies such as GSK, Bristol-Myers, Takeda and Eisai also partner with local and regional hospitals to run and coordinate trials from and inside Singapore. [2]
- C.44 Finally, expertise in drug discovery and development within the Experimental Therapeutics Centre (ETC) has helped to translate basic science discoveries into proof of concept projects in order to make them more attractive for out-licensing to industry or for the formation of new enterprises.

### ***Key learning***

- C.45 A\*STAR has a mission to drive and sustain world-class scientific research but linked and closely integrated with economic development objectives. [1]

### ***Competitive positioning***

- C.46 The collaboration of A\*STAR with CIMIT was seen as a way to enhance esteem and the environment for growing the medical technology industry as part of the drive to transform Singapore into a knowledge-based innovation-driven economy. This alliance is part of A\*STAR’s goal in fostering a “vibrant medical technology innovation ecosystem”.

### ***Routes to economic outcomes and impacts***

- C.47 The Singapore Biomedical Sciences (BMS) initiative was launched in June 2000 to develop the biomedical sciences cluster as one of the key pillars of Singapore's economy, alongside electronics, engineering and chemicals. Three agencies work in close coordination and in an integrated fashion to develop the BMS cluster [1]:

- the Biomedical Research Council (BMRC) part of A\*STAR funds and supports research initiatives.
- the Economic Development Board's (EDB) Biomedical Sciences Group (BMSG) promotes private sector manufacturing and R&D activities, whilst its Bio\*One Capital functions as the biomedical investment arm of EDB.
- the Ministry of Health's (MOH) National Medical Research Council (NMRC) funds and supports public research initiatives, as well as awarding medical research fellowships for the development of the medical research labour pool.

C.48 A\*STaR's role involves developing three types of capabilities [1]:

- *human capital* – with over 2,300 researchers, 50% are international, from over 50 countries.
- *intellectual capital* – to facilitate knowledge exchange and to push scientific boundaries.
- *industrial capital* – to exploit commercial markets to the benefit of Singapore.

C.49 Translational research capability and activity in Singapore is described as evolving over two phases, as described below<sup>35</sup>.

*Phase 1 (2000-2005): Building the Foundation*

C.50 The first phase of development focused on establishing a firm foundation of basic biomedical research in Singapore. Five research institutes developed core research capabilities in the areas of bioprocessing, chemical synthesis, genomics and proteomics, molecular and cell biology, bioengineering and nanotechnology, and computational biology. In a partnership between BMRC and sister council, the Science and Engineering Research Council, the Institute of Chemical and Engineering Sciences' Chemical Synthesis Laboratory @ Biopolis was established to provide cognate capabilities in chemistry. All these support the BMS cluster, comprising the four key sectors: pharmaceuticals, biotechnology, medical technology and healthcare services.

*Phase 2 (2006-2010): Strengthening Translational and Clinical Research Capabilities*

C.51 The second phase of development has focused on strengthening capabilities in translational and clinical research, whilst continuing to build up basic research capabilities. BMRC's Singapore Institute for Clinical Sciences (SICS) and Institute of Medical Biology (IMB) conduct translational and clinical research to “bridge the gap between bench and bedside”.

C.52 BMRC has also launched consortia initiatives which place significant emphasis on translational research in areas such as the Singapore Cancer Syndicate (SCS), Singapore

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<sup>35</sup> Quoted directly from A\*STaR (<http://www.a-star.edu.sg/AboutASTAR/BiomedicalResearchCouncil/BMSInitiative/tabid/108/Default.aspx>)

Bioimaging Consortium (SBIC), Singapore Stem Cell Consortium (SSCC), Singapore Consortium of Cohort Studies (SCCS) and Singapore Immunology Network (SiGN).

C.53 Economic impact is also pursued through support for commercialisation. A\*STaR drives the commercialisation of research, through three entities [1]:

- *Exploit Technologies Pte Ltd* (ETPL) manages the intellectual property portfolio to promote transfer of research to industry
- *Experimental Therapeutics Centre* (ETC) aids in translating scientific discoveries into practical applications by engaging in early stage research and creating public-private partnerships etc.
- *BMRC Industry Development Group* (IDG) facilitates research from early stage concepts to commercial products

C.54 The integrated (multi-disciplinary) approach to research and translational studies is illustrated in Figure C-2 [1].

Figure C-2 : Diagrammatic representation of Singapore's integrated approach to translational research.



Source: A\*STaR - Agency for science Technology and Research, Singapore

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## Pennsylvania

C.55 Penn Medicine is a \$2.9 billion enterprise dedicated to the related missions of medical education, biomedical research and high-quality patient care. Penn Medicine consists of the School of Medicine at the University of Pennsylvania (UoP) and the University of Pennsylvania Health System, which includes three hospitals. As part of Penn Medicine, the Institute for Translational Medicine and Therapeutics (ITMAT) at the University of Pennsylvania was launched in 2005 to support research at the interface of basic and clinical research. ITMAT has now expanded to include all investigators focused on clinical and translational research in UoP, the Children's Hospital of Philadelphia, the Wistar Institute and the University of the Sciences in Philadelphia.

Table C-4 : Summary of the logic model for Pennsylvania

Step	Description	Measures used	Comments
Rationale	To support research at the interface of basic and clinical research focusing on developing new and safer medicines. [1]		
Objectives	<p>ITMAT was designed to cluster the many existing entities which support translational research [1]</p> <p>ITMAT originally focused on research to span the translational gap from proof of principle in model systems to completion of studies of drug mechanism and dosing in humans at the conclusion of Phase II.</p> <p>The two major areas of focus are [1]:</p> <ol style="list-style-type: none"> <li>1. translational therapeutics</li> <li>2. bridging the Pediatric to the Adult divide in understanding of physiology and disease.</li> </ol>	ITMAT includes the Clinical and Translational Research Center (CTRC), which now also incorporates the former General Clinical Research Center (GCRC) of UoP and the Children's Hospital of Philadelphia (CHOP). [1]	
Inputs	Expertise and funding, plus co-ordinated use of existing infrastructure	<ul style="list-style-type: none"> <li>• ITMAT includes more than 700 investigators, from the UoP, the Children's Hospital of Philadelphia, the Wistar Institute, and the University of Sciences in Philadelphia. [1]</li> <li>• funding for ITMAT comes from the partner institutions and the Clinical and Translational Science Award (CTSA) funded under the NIH Roadmap, and other sources of extramural support. [1]</li> <li>• the NIH has recently awarded Penn Medicine \$68m and CHOP \$30m [2]</li> </ul>	
Outputs	There are references to delivery of enhanced research infrastructure, knowledge exchange activities and clinical trials	<ul style="list-style-type: none"> <li>• In 2010 the new, \$370-million Anne and Jerome Fisher Translational Research Center at the University of Pennsylvania is due for completion to house 100 principle investigators</li> </ul>	

Step	Description	Measures used	Comments
		<p>and 900 research staff. This will be the first medical research building physically integrated with patient care facilities at Penn. [3]</p> <ul style="list-style-type: none"> <li>ITMAT is now home for new Centres in [1]: <ol style="list-style-type: none"> <li>Bioinformatics in Translation (BIIT)</li> <li>Personalized Medicine in Translation (PERMIT)</li> <li>Chemical Biology in Translation (CBIT)</li> </ol> </li> <li>Launched its International Spring Symposium Series in 2006 [1]</li> <li>ITMAT has also sponsored workshops and funding support for interdisciplinary, translational programs [1]</li> <li>Penn Medicine currently has 609 active clinical trials [4]</li> </ul>	
Outcomes	Patenting and projects in the drug discovery pipeline. Also reports on products established by local businesses.	<ul style="list-style-type: none"> <li>33 Patents filed last year (2009)</li> </ul> <p>The following provides an indication of the level of research activity within the drug discovery pipeline in Pennsylvania. This provides the number of companies from Pennsylvania with the total number of products across different therapeutic areas (from development to market products) [5]:</p> <ul style="list-style-type: none"> <li>25 companies have 259 products in 40 therapeutic areas such as Colorectal cancer, Melanoma, Lymphoma, Multiple Myeloma, and Solid tumors.</li> <li>More than 25 companies have 206 products in 35 therapeutic areas such as for Alzheimer's disease, Multiple Sclerosis, Pain, and Parkinson's disease.</li> <li>Over 15 companies have 257 products in 58 therapeutic areas such as Bacterial Infections, Cytomegalovirus infections, Hepatitis B, and Influenza.</li> <li>more than 15 bioscience companies have 53 products in 14 therapeutic areas such as Type II Diabetes, Diabetic Neuropathy, and Obesity.</li> <li>24 companies have 51 products to treat 38 rare diseases such as Acute Myelogenous Leukemia, Cystic Fibrosis, Gaucher's disease, and Stomach cancer.</li> <li>There are 13 bioscience companies developing vaccines, including GSK, Immunotope, MedImmune, Merck, and sanofi pasteur. The 168 products prevent 45 conditions including AIDS/HIV, Cervical cancer, Hepatitis B, and Meningitis.</li> </ul>	

Step	Description	Measures used	Comments
Impacts	Reported in terms of overall employment, investment and economic output.	<p>Using the Greater Philadelphia area as an example of the State of Pennsylvania (containing Penn Med etc) [6]:</p> <ul style="list-style-type: none"> <li>the area's Life Sciences sector generated \$7.7 billion in earnings and \$17.5 billion in output or gross metro product (GMP) in 2007. In both cases, the therapeutics and devices segment accounts for the largest share of the earnings and output created by the overall Life Sciences sector.</li> <li>after accounting for the ripple effects, the Life Sciences sector in Greater Philadelphia was responsible for generating 380,800 jobs, \$20.2 billion in earnings, and \$39.7 billion in output in 2007.</li> <li>fifteen percent of all economic activity and one out of every six jobs in Greater Philadelphia can be traced back to the Life Sciences.</li> </ul>	Hard to attribute to specific initiatives from the information available.

### Key learning

C.56 Current initiatives are benefiting from decades of capability building and reputation as an area with leaders in the field, for example:

- the University of Pennsylvania - School of Medicine (Penn Medicine) was founded in 1765 as the nation's first medical school and is ranked second in the USA for NIH research funds, averaging \$500m per annum. It supports 1,700 full-time faculty members and 725 medical students, and is recognized worldwide for its superior education and training in the fields of medicine. [7]
- the Children's Hospital of Philadelphia was founded in 1855 as the nation's first paediatric hospital. Its paediatric research programme is among the largest in the country, ranking third in NIH funding. The CHOP accommodates over 525 principal investigators and nearly 1,500 research scientists. In 2009, the CHOP secured \$109,275,686 in federal funding and \$141,332,305 from external awards. The CHOP has been associated with pioneering research in paediatric medicine, such as the development of vaccines against measles, mumps and rubella. [8]
- the University of Pennsylvania Health System includes three hospitals, one of which was the USA's first hospital [2]
- the Wistar Institute is an independent non-profit biomedical research institute and was the first institute of its kind in the USA devoted to medical research and training. The Wistar has led to developments in vaccines for rabies and rubella, and in gene identification in different cancers. [9]



### Competitive positioning

- C.57 History, tradition, excellence and scale are all key factors in the competitive positioning. Much is made of success in attracting research investment from ‘high value’, esteemed sources such as the NIH.
- C.58 The University of Pennsylvania is the oldest and promoted as one of the finest medical schools in the United States. It is rich in tradition and heritage and at the same time consistently at the forefront of new developments and innovations in medical education and research. Since its founding in 1765, the School has prided itself in having a strong presence in the community and in educating tomorrow’s leaders of in patient care, biomedical research and medical education. [1]

### Routes to economic outcomes and impacts

- C.59 The Penn Med has built up a long history of working with closely allied and prestigious organisations. The formation of ITMAT was an explicit move to coordinate translational medicine across these existing partners.
- C.60 The report [9] on the Greater Philadelphia Life Sciences Cluster 2009 provides a detailed description of the economic impact on the Greater Philadelphia area which is home to the main organisations listed here including the University of Pennsylvania (i.e. Penn Med). The critical success factors for this region are succinctly stated as:

*“The growth of Greater Philadelphia’s Life Sciences cluster is primarily the result of its position as a major center for the U.S. pharmaceutical industry and its strong local research infrastructure, which includes some of the nation’s top-ranked universities. The region’s eclectic mix of university research, world-renowned teaching hospitals, technology spin-out companies, and other startups—all interacting in a network—encourages companies to establish operations and grow in Greater Philadelphia. Underpinning all this interconnected activity is an evolving support network for entrepreneurs, including venture capitalists, high-tech absorptive capacity, and providers of professional services.”*

- C.61 What is notable here is the emphasis on an integrated – a ‘systems’ approach – to economic development. These multiple factors are seen as key in providing a sustained innovation pipeline and to facilitate technological advance and commercialisation. There is for example much emphasis given to the importance of investing in three types of ‘capital’– financial, human and infrastructural.
- C.62 As indicated in the table above, it is hard to attribute impact to specific initiatives from the information available. However, the 2009 report on the Greater Philadelphia Life Sciences cluster [6] indicates how over impact is being assessed. This ‘technical’ report uses the following benchmarking parameters to develop what is termed a ‘Current Impact Composite Index’:

#### Size and Performance

- Employment level: the employment level of each NAICS code measured to ascertain the actual number of workers in these industries



- Location quotient (LQ): to measure the share of employment of a specific industry with respect to the national share. A location quotient of more than 1.0 indicates that the region has a higher relative concentration of that industry's employment than the national average (taken as 1.0)
- Relative growth: to look at the current level of employment indexed to its base year, and then taken as a proportion of the indexed growth in this particular field throughout the United States
- Life Sciences establishments per 10,000 total establishments: this shows the share of total establishments engaged in Life Sciences

#### Diversity

- number of Life Sciences industries with LQs greater than 2.0: to ascertain the number of Life Sciences industries in a region that have at least twice the employment concentration locally as they do throughout the United States
  - number of Life Sciences industries with LQs less than 0.5: to ascertain the number of Life Sciences industries in a region that are 50 percent or below the employment concentration found throughout the United States
  - number of fast-growing Life Sciences industries: this refers to the number of Life Sciences industries in a region that grew faster locally than across the United States as a whole within the five-year period.
- C.63 The first four components focus on issues of size and performance, while the latter three measure diversity. The use of this 'Current Impact Composite Index' comprising these seven components is used to provide a relative snapshot of the current economic impact or outcome of Greater Philadelphia relative to other US locations.
- C.64 There is merit in a closer examination of this cluster impact assessment, including for its insights into the role and multiplier effects achieved by R&D in the medical Life Sciences.

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## Sweden

- C.65 The scale of the TCM sector in Sweden can be viewed at a sub-regional level for the east coast (surrounding Stockholm) and the west coast (surrounding Gothenburg). Additionally, Sweden is known for developing its biomedical capabilities at a trans-national (cross-border) level in partnership with Denmark, in the so-called Øresund Science Region (OSR) at the Southern tip of Sweden.

### **Sweden's east coast – the Karolinska Institute Science Park**

- C.66 The KI Science Park is closely associated with the Karolinska Institute, Sweden's largest centre of medical training and research, and also one of Europe's largest medical universities. The KI Science Park is situated over two separate campus sites:
- *Campus Flemingsberg*, in the South of Stockholm, is next to the Royal Institute of Technology (KTH) and Södertörn University, with the Karolinska University Hospital. The KI Science Park is situated in the centre of what will become the future research centre (Biocity) currently at the planning stage of construction.
  - *Campus Solna* has a new university hospital under construction (for completion in 2015) to support the biotech hub of Stockholm Science City. The goal is to establish a world-leading Life Sciences area with immediate proximity to the Karolinska Institute and the New Karolinska Solna university hospital. A total of about five billion euros are expected to be invested in a wide range of projects during the next fifteen years. [2]
- C.67 Start-up companies are promoted through Karolinska Institute Innovations (AB) through support towards full commercialisation. Much is made of the entrepreneurial nature of the institution and of its success in generating spin-out companies.

Table C-5 : Summary of the logic model for east Sweden

Step	Description	Measures used	Comments
Rationale			
Objective s	To become the most attractive growth environment in Scandinavia for developing companies in the fields of Life Science,		

Step	Description	Measures used	Comments
	Medical Technology and Service Production.		
Inputs	The resources (people, infrastructure, financial investment etc.) of: <ul style="list-style-type: none"> <li>• Campus Flemingsberg</li> <li>• Campus Solna</li> </ul>	<ul style="list-style-type: none"> <li>• At Campus Solna, a total of 5 billion euros is expected to be invested in projects over the next 15 years. [2]</li> </ul>	
Outputs	Strong emphasis on commercialisation outputs and outcomes	<ul style="list-style-type: none"> <li>• To date, over 40 start-up companies have been created, and 30 licensing agreements secured.</li> </ul>	
Outcomes		<ul style="list-style-type: none"> <li>• Karolinska Institutet and Affymetrix have entered a five-year strategic alliance, which includes projects in patients with atherosclerosis, breast cancer, rheumatoid arthritis, asthma and dyslexia. The goal of the alliance is to develop diagnostic and prognostic tools. [3]</li> </ul>	
Impacts			

### Key learning

- C.68 The Karolinska Institute as one of Europe's largest medical universities provides an internationally renowned anchor organisation for the KI Park.

### Competitive positioning

- C.69 The vision for the Karolinska Institute (KI) Science Park (AB)<sup>36</sup> is: "to have the ambition to become the most attractive growth environment in Scandinavia for developing companies in the fields of Life Science, Medical Technology and Service Production, with the science park as: "the natural choice for both national and international innovative research companies who wish to establish themselves in the region or to develop their existing business." [4]
- C.70 This place-related focus has parallels with Edinburgh Bioquarter.

### Routes to economic outcomes and impact

- C.71 The clustering effect of healthcare capabilities that have built up around the Karolinska Institute are now being 'replicated' at Campus Solna with the construction of a new university hospital.
- C.72 The routes include attracting inward investment to the science parks and through commercialisation of research, notably through spinouts.

### Sweden's west coast - GöteborgBIO

- C.73 The City of Gothenburg (Göteborg) is cited as being: "one of Europe's most important clusters for Life Sciences and biomedicine" derived from a strong academic base, a major

<sup>36</sup> The Novum Research Park was recently renamed. Prior to the 1<sup>st</sup> March 2007, the Karolinska Institute Science Park was formally referred to as the Novum Research Park (Novum Biocity).

industrial presence and a focus on translational medicine through collaborative research with the hospital establishments [4].

C.74 The GöteborgBIO is a joint project operating at the national and regional levels to nurture academic research and commercial innovations within the healthcare system, with specialisms in biomaterial, cell therapy and cardiovascular and metabolic diseases.

C.75 Principal organisations within GöteborgBio are [5]:

- academic institutes:
  - the Chalmers University of Technology and the University of Gothenburg. The Sahlgrenska Academy is the medical faculty within the University of Gothenburg with an international reputation
- hospitals:
  - Sahlgrenska University Hospital is one of six teaching hospitals with medical education in Sweden and has strong linkages with the Sahlgrenska Academy. These two organisations are conducting nearly 300 joint research projects in areas such as obesity, cardiovascular research, diabetes, biomaterials, pharmacology, neurosciences, pediatrics, epidemiology, rheumatology and microbiology.
- industry:
  - the region accommodates c.170 Life Science companies [5]. AstraZeneca and GSK are also present in the region. Private sector firms active in GöteborgBio (BMV), include [4]:

AstraZeneca (pharmaceuticals, drug discovery, clinical trials etc)

Mölnlycke Health Care providers of single-use surgical products and healthcare services.

Nobel Biocare as a provider of innovative restorative and aesthetic dental solutions.

8.35 The Biomedical development of Western Sweden by BMV is a ten year plan starting in 2005 [6].

Table C-6 : Summary of the logic model for west Sweden

Step	Description	Measures used	Comments
Rationale	The strategic concept for BMV is to create structure and develop tools, platforms and processes to bring world class academic research into innovations in industry and to implementation in health care. [6]		
Objectives	GöteborgBIO aims to create a solid base for long-term growth in the biomedical field within the region, by cultivating academic research and commercial innovations and adaptations within the health care system; more specifically to [6]: <ul style="list-style-type: none"> <li>• reinforce need driven R&amp;D within two areas of international strength of:</li> </ul>		

Step	Description	Measures used	Comments
	<ul style="list-style-type: none"> <li>➤ Biomaterials &amp; Cell Therapy</li> <li>➤ Cardiovascular &amp; Metabolic Science</li> <li>• Attract qualified and competent persons and investment capital to the region.</li> <li>• Increase the availability of trained leaders for advanced business creation for biomedicine.</li> <li>• Strengthen and develop the infrastructure for commercialization within biomedicine.</li> <li>• Develop a process for efficient learning within the innovation system</li> </ul>		
Inputs	Inputs include research, infrastructure, investment and other forms of business support	<p>Contributions by [5]:</p> <ul style="list-style-type: none"> <li>• Chalmers University of Technology</li> <li>• University of Gothenburg and the Sahlgrenska Academy</li> <li>• Sahlgrenska University Hospital</li> <li>• Private enterprise, including AstraZeneca, Mölnlycke Health Care and Nobel Biocare</li> <li>• VINNOVA - Swedish Governmental Agency</li> <li>• Business Region Göteborg</li> <li>• Region Västra Götaland</li> <li>• Innovationsbron Väst</li> </ul>	
Outputs	Reported in terms of collaborative projects; knowledge transfer activities; establishment of incubator facilities, networking and international partnership agreements.	<p>In the first three years of the 10 year plan for Western Sweden [6]:</p> <ul style="list-style-type: none"> <li>• results from 3 collaborative projects within biomaterials and cell therapy have been published in peer-reviewed journals and presented at scientific conferences.</li> <li>• an international scientific conference organized within biomaterials &amp; regenerative medicine.</li> <li>• 17 innovation projects cardiovascular and metabolic sciences received support from BMV and leveraged support into a total of 26 MSEK in additional grants and investments from national and international funding agencies and investors.</li> <li>• the incubator at Sahlgrenska Science Park has expanded with 6 companies and over 20 projects supported. Additional incubator space was constructed in 2007.</li> <li>• close to 1000 people participated in 13 seminars to build networks in the region.</li> </ul>	

Step	Description	Measures used	Comments
Outcomes		<ul style="list-style-type: none"> <li>creating a greater understanding in the fields of Biomaterials &amp; Cell Therapy and Cardiovascular &amp; Metabolic Science.</li> <li>identification of crucial gaps within the innovation system; knowledge and competence in the fields of business, project management and regulatory affairs.</li> <li>International networks created. Signed collaborative agreements with a number of regions including the states of North Carolina and Michigan in the USA, and the city of Shanghai in China. Also established a Göteborg-Oslo Initiative. [6]</li> </ul>	
Impacts	Reported in terms of 'esteem'/prizes; products developed; inward investment.	<p>Regarding the region [7]:</p> <ul style="list-style-type: none"> <li>Professor Arvid Carlsson received the Nobel Prize in 2000 for his research into the dopamine system, which has contributed the region's rise to prominence.</li> <li>Several best-selling drugs have been developed for these diseases, including Losec and Nexium for the treatment of gastrointestinal diseases and Seloken/Toprol, Plendil and Crestor for the treatment of cardiovascular diseases, all from AstraZeneca.</li> <li>AstraZeneca has its global headquarters for cardiovascular and metabolic diseases located in the Göteborg region. It is one of the largest and most modern sites in Europe for pharma R&amp;D. Almost 3,000 people are involved in finding new therapies within this field.</li> </ul>	

### Key learning

- C.76 As with many of the other places reviewed, there is a focus on integrated (cluster) development. Reference is made to an organic growth of the 'Triple Helix' framework involving university, industrial and hospital research in healthcare, supported closely by Government and local agencies and enabled by the presence of internationally recognised organisations and institutes.
- C.77 There is also an emphasis on developing global networks.

### *Competitive positioning*

- C.78 The vision of BMV is that the Göteborg region by the year 2015 will be known as one of Europe's most innovative and expanding regions for industrial development and evidence-based application of new knowledge and innovations in the field of biomedicine.

### *Routes to economic outcomes and impact*

- C.79 The main route to economic impact has been established through the adoption of Triple Helix framework for strategy development and implementation enabled by engagement of highly reputable business partners and longstanding research organisations.

## **The Øresund Science Region**

- C.80 The Øresund Science Region (OSR) is a trans-national (cross-border and inter-city) collaborative initiative between industry, universities and the public sector of Greater Copenhagen in Denmark and the Skane region (which includes Malmö and Lund urban areas) in south west Sweden. This area comprises some of the most advanced and depressed areas in both countries [8].
- C.81 The fundamental aim is to develop a number of industrial-innovation technology platforms, in which the OSR has a comparative advantage, in order to secure the region's position as a major node in the global knowledge-based economy. In 2000, a new road/rail bridge across the Øresund Strait was completed, linking Denmark and Sweden. The OSR was established in 2001.
- C.82 It is governed by a Board of 18 members, comprising academic, commercial and civic representatives, half from each country. The most successful example of this trans-national alliance is in the biotech/medical sector, named Medicon Valley which is represented and co-ordinated by the Medicon Valley Alliance (MVA) [8].
- C.83 Medicon describes itself in the following way:

*“As the Danish-Swedish, non-profit cluster organisation representing human Life Sciences in Medicon Valley, MVA is committed to facilitating economic growth, increased competitiveness, and employment in Medicon Valley, and furthermore committed to raising the recognition of Medicon Valley to attract foreign key stakeholders.*

*We will accomplish this by:*

- *building local and global platforms for networking for both academia and business.*
- *organising events and seminars with the objective of improving knowledge and competencies among Medicon Valley's stakeholders.*
- *creating an overview of the on-going development of Medicon Valley for the benefit of international and local stakeholders.*
- *analysing and proposing solutions for the improvement of the Life Science environment in Medicon Valley.*



*All our initiatives are based on the belief that being an active part of a leading global Life Science cluster and having unique and privileged access to top ranked Life Science clusters worldwide will improve the conditions for the Medicon Valley stakeholders; primarily, for taking research and business in Medicon Valley even further.”*

C.84 Notably in addition to its c. 9 professional staff, the Medicon web site lists on its staff page, c. 7 ‘Life Science ambassadors’. Four clusters internationally are presently directly linked through the exchange of Life Science ambassadors. Eight other clusters are currently linked by close cooperation between the respective cluster organisations. (See: [http://www.ambassadorprogramme.com/content/us/about\\_the\\_programme](http://www.ambassadorprogramme.com/content/us/about_the_programme) for more information on this programme).

C.85 The expected outcomes of the Programme are stated as:

- improved privileged access to the top Life Science innovation environments in the world
- increased level of foreign investment into the most promising business and projects
- improved validated network of commercial and scientific contacts
- increased innovation and competitiveness through strategic partnerships and international alliances for both companies and academics
- job creation through increased competitiveness and innovation.

Table C-7 : Summary of the logic model for the Medicon and Oresund area

Step	Description	Measures used	Comments
Rationale	An economic push was required to counter the decline of traditional manufacturing in the 1980s and to address high unemployment. [9]		
Objectives	<p>To form an alliance between regions of Denmark and Sweden to create a critical mass in high technology sectors through complementary capabilities to compete in global markets. To utilise the OSR as an economic development strategy. More specifically, is to [9]:</p> <ul style="list-style-type: none"> <li>• develop efficient cross-border ways of producing and monetising knowledge and innovation</li> <li>• develop critical mass in a handful of high technology platforms, with globally significant capacities, capabilities and impact</li> <li>• develop the OSR as a major node in the European and global knowledge-based and innovation economy</li> <li>• identify and support emerging clusters with potential to be ‘world-class’</li> <li>• establish state-of-the art scientific networks and co-operative regimes</li> <li>• develop the OSR as both environmentally sound and as socially inclusive as possible.</li> </ul>		Medicon is just part of a much larger trans-national initiative but appears to have been one of its more successful and high profile achievements

Step	Description	Measures used	Comments
Inputs	<p>Collectively, this cross-border partnership provided a critical mass of [9]:</p> <ul style="list-style-type: none"> <li>• 14 Universities (co-ordinated by Oresund University) and a further 22 university colleges</li> <li>• 6 major Science Parks</li> <li>• 6 Incubator facilities</li> <li>• 32 major hospitals – 11 of which are university hospitals</li> <li>• Around 150,000 students; 6,500 PhDs; over 12,000 private and public sector researchers</li> <li>• 5 major clusters or 'technology platforms' including that of <i>Oresund Life Science</i><sup>37</sup></li> <li>• 5 airports, with Copenhagen as a major international airport)</li> <li>• Medicon Valley – the most successful OSR cluster / high technology platform: <ul style="list-style-type: none"> <li>• Over 25 major pharmaceutical companies</li> <li>• Around 100 biotechnology companies</li> <li>• Around 100 medtec companies</li> <li>• Over 40,000 employees in private sector Life Science companies</li> <li>• 45,000 students in 'Life Sciences'; 7,500 graduate students p.a.</li> </ul> </li> <li>• Over 50 contract research / manufacturing organisations in Life Sciences</li> <li>• 210 Venture Capital organisations</li> </ul>	<p>Nationally, a 3.1% GDP investment by Sweden and Denmark in R&amp;D across the two countries (beyond OSR)</p> <p>Within the OSR [9]:</p> <ul style="list-style-type: none"> <li>• networking OSR Triple Helix members and international agents</li> <li>• branding, promotion and marketing to attract new firms, capital and talent to the OSR</li> <li>• promote and fund research into new technologies and generate university spin-outs</li> <li>• accelerating commercialisation of Intellectual Property</li> </ul>	
Outputs	Expressed as knowledge/technology transfer achievements.	<ul style="list-style-type: none"> <li>• 15,000 peer review articles annually</li> <li>• 55 patent applications</li> <li>• 176 inventions disclosures</li> </ul>	
Outcomes	Expressed in terms of capacity/scale development for the cluster; international benchmarking parameters; education/skills attainments.	<p>Outcomes have been identified as [9]:</p> <ul style="list-style-type: none"> <li>• the OSR Life Science cluster represents about 60% Scandinavia's Life Science capacity.</li> <li>• the OSR now ranks third behind London and Paris in biotechnological and medical research.</li> <li>• greater education attainment and skills rates within the OSR.</li> </ul>	
Impacts	As the Life Sciences platform has now been separated from the platform clusters identified	<ul style="list-style-type: none"> <li>• a steady increase in GDP per capita, rising from EUR</li> </ul>	

<sup>37</sup> Since the publication of the SQW report [Reference 8 herein] the formal recognition of the *Oresund Life Science* platform has been 'dropped' from the defined OSR platforms (of logistics, ICT food and the environment), but still exists through the Medicon Valley Alliance (<http://www.mva.org/content/us/initiatives> )

Step	Description	Measures used	Comments
	by the OSR, it is difficult to obtain information relating to recent impacts by this spatial geography. Additionally, the Annual reports produced by the MVA are in not transcribed in English]	19,000 in 1995 to EUR 28,000 in 2005-2006. Impacts of the OSR have transformed Medicon Valley in becoming [10]: <ul style="list-style-type: none"> <li>ranked in the top 10 European regions for biotechnology &amp; applied microbiology, immunology &amp; oncology by research publications.</li> <li>ranked the 10th most productive European region in terms of its biotechnology patenting</li> <li>the region has a significant presence at every stage in the drug development chain</li> </ul>	

### Key learning

C.86 The following learning points are relevant:

- emphasis on effective collaboration and the exploitation of complementarities underpins the development of critical mass in high technology platforms in the OSR. Successful collaboration has been adopted within the OSR but with other high ‘technology hotspots’ around the world [9]
- emphasis on achieving good governance and the development of an effective Triple Helix organisation, enhanced through the presence of key anchor commercial organisations as well academic and health institutes [9]
- strong support by Governments but driven by a bottom-up approach for both scientific growth and economic regeneration [9]
- the development of an effective regional/OSR innovation ecosystem (including effective technology transfer mechanisms managed by the universities) and facilitation of knowledge sharing both within the OSR and with other technology hotspots around the world. [9]

### Competitive positioning

C.87 The Medicon Valley Alliance has a vision for Medicon Valley to become among the five most attractive bioregions worldwide, recognised for [11]:

- an excellent scientific environment and pool of talent
- outstanding access to knowledge sharing and technology transfer between universities, hospitals and industry
- an innovative and entrepreneurial environment, with competitive enterprises

- a truly international perspective and global network.

#### *Routes to economic outcomes and impact*

C.88 The proposed routes to economic impact are epitomised by three key factors:

- the successful adoption of the Triple Helix framework
- the vision to work in a trans-national partnership to create a critical mass in high-technology and high value markets to compete at international level (creating a new model for regional systems of innovation)
- to focus on utilising complementary capabilities housed within key anchor organisations (public and private sectors) across the two countries.

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