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Commercialisation of Innovations from the UK National Health Service

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Abstract:

The potential opportunities offered by developing innovative ideas from staff within the UK National Health Service (NHS) was recognised in 2000 and this paper describes a regional organisation, Medipex, which was set up to undertake technology transfer and commercialisation of innovations from the NHS in Yorkshire. The approach adopted by Medipex has been shown to be a successful model for the commercialisation of IP, obtaining private sector investment and winning external recognition after its first three years trading. Analysis of the outputs demonstrates that though the majority of ideas emerge from service use, the innovations which have high-value commercial potential emerge from research undertaken in the hospitals.

Keywords: Technology transfer; commercialisation; medical technology, public health sector; organisational model

Biographical notes:

Mike Smith is a Professor of Medical Physics with 25 years experience in research and exploitation in the medical and health sector, with a focus on the development of non-invasive investigative techniques in medicine and their application in a wide range of clinical applications. He has served on a number of National Committees including: NHS Central R&D Committee; NHS New and Emerging Applications of Technology (NEAT) Advisory Board; and NHS R&D Standing Group on Health Technology Assessment. He has experience in patenting, licensing and commercialising IP in medical technology. He has held many non-executive positions with commercial organisations. He was the founder of Medipex and is now a non-executive director.

Richard Clark is currently CEO of Medipex. He is a business development strategist who in the last 15 years has established 3 companies associated with knowledge transfer, worked with numerous medical technology spin out companies and was responsible for the establishment and operation of the first Medilink. His career spans over 30 years as a chartered engineer in project management in diverse sectors including energy, environmental industry and most recently in medical engineering. He has published over 15 technical papers, acted as an international environmental consultant, been co-chair and presented papers at numerous international conferences and has several patents to his name.

1 Background

The UK National Health Service (NHS) was set up in 1948 to provide universal healthcare and is the largest public funded health service in the world; it is also the largest organisation in Europe and between the 3rd and 5th largest organisation in the world. The nature of its workforce, many of which are highly skilled and leaders in their field, coupled with its size, provide an environment where innovations can develop and emerge from both research and experience of delivering patient care. Such innovations could be of commercial value, or of value to the NHS to support its core business. However the fact that the NHS is a massive public sector organisation, unused to working in a commercial entrepreneurial environment, posed unique problems in these areas.

In the 1990s the NHS had developed a coherent R&D strategy for the first time (Shergold and Grant, 2006) which set out to formalise and encourage R&D, supporting research across a range of activities including health technology assessment (Smith, 1996) and support for new and emerging applications of technology. In addition, in the late 1990s, it was recognised that the healthcare sector should be yielding significantly higher levels of exploitable intellectual property (IP) than was actually being realised; coupled with this the NHS was concerned that IP was leaking from the NHS, either directly to commercial companies or to the University sector, without benefit to the NHS. Also during this period the potential opportunities associated with technology transfer and the commercialisation of innovations at a more general level, was recognised.

For many years University technology transfer offices (UTTOs) have performed the function of transferring technology and commercialising innovations emerging from the University sector but entrepreneurship theory and research on the role of the UTTO for the commercialisation of innovations is sparse (Markman et al, 2005). The literature which does exist generally offers a theoretical and critical analysis of the literature and policy documents associated with technology transfer and commercialisation (Bozeman, 2000), sometimes focussing on the healthcare sector (Savory, 2006). Comparable organisations to UTTOs generally do not exist in the healthcare sector though often UTTOs will undertake work in a healthcare field, often when the University has a medical school which has relationships with hospitals. This is despite many innovations emerging from the hospital environment rather than the University environment.

When the initiative described in this paper commenced there was no firm published evidence directly related to technology transfer and commercialisation in a public health sector. This paper describes a specific approach, and the first five years experience, to the commercialisation of IP emerging from the health sector, which has sought to address the problem of working at the interface of a very large public sector organisation and the commercial sector. No attempt has been made in this paper to identify the potential cost savings to the NHS or of the economic impact of better patient outcomes which will be the next phase of this study.

2 Formation of an Organisation to Commercialise IP from the NHS

2.1 *Initial analysis*

The analysis undertaken in 2001 highlighted a number of factors which needed to be taken into consideration if the commercial potential of IP emerging from the NHS were to be realised. The first was the breadth of activities that would need to be supported: education and training, identification and filtering of IP, protection of IP, management of IP for the NHS and commercial exploitation. In addition, opportunities were identified for the non-commercial exploitation of innovations of value to the NHS itself and the commercialisation of the knowledge and expertise base in the NHS. The second was the public sector culture of the NHS which, from a technology transfer and commercial exploitation perspective, would be perceived as essentially cautious, risk averse, and slow to make decisions. Not only would the necessary processes to make decisions not be in place, but the inherent governance arrangements would operate in a slow timeframe. Thirdly the output from a single

hospital would be insufficient to support the necessary investment and, in order to achieve the critical mass, a consortium of hospitals would be required.

An option appraisal of the following business models was undertaken: (i) a unit based within a Hospital, (ii) a company limited by guarantee (iii) a charitable Trust or (iv) a partnership with an existing non-NHS organisation. As it was considered essential to adopt private sector governance disciplines rather than public sector governance the option of a unit based within a hospital was not pursued. An existing non-NHS organisation, which could provide the range of customised activities required, could not be identified and so that option was not pursued. Of the remaining two options a company limited by guarantee (CLG) provided the most appropriate business model to enable access to both public and private investment. A further advantage was perceived to be the independence of the CLG from any one organisation, thus helping the formation of a consortium of NHS organisations

2.2 *Creation of Medipex*

A proposal was prepared in spring 2001 to seek funding to become one of the NHS's regional organisations to commercialise IP. The Hospital Trusts that formed the consortium had a strong interest in participating with the initiative, were in receipt of significant NHS R&D levy income, represented different perspectives within the NHS and had strong links with their local Universities. The consortium was led by the Leeds Teaching Hospitals NHS Trust with five other partners: Sheffield Teaching Hospitals Trust, Bradford Hospitals NHS Trust, Hull and East Yorkshire Hospitals NHS Trust, York Health Services NHS Trust and Barnsley District General Hospital NHS Trust (see Figure 1). Written support was also received from many regional organisations.

Two specific public sector funding initiatives combined to support technology transfer and commercialisation in the NHS. The first was funding from the NHS R&D budget to create regional initiatives in technology transfer and commercialisation coupled with policy and guidance for dealing with intellectual property (IP) (DH, 2002). Funding for these was supplemented from a second, broader funding initiative from the Department of Trade and Industry which had been prompted by a report by Baker (1999); this was the Public Sector Research Establishment (PSRE) funding initiative which has been repeated on three occasions since 2001. These regional initiatives to support technology transfer and commercialisation in the NHS were initially christened 'IP Hubs' and, more recently, are referred to as 'Innovation Hubs'. Different operating models were adopted across the UK.

Before 2001, NHS Trusts were not allowed to hold equity in companies and the necessary legislation to enable this to happen was approved in 2001. Unfortunately there was a delay in the enactment of the legislation, eventually extending to 18 months, which imposed a delay in the formation of the CLG.

Medipex was formed as a CLG in 2003, the first company to be formed associated with the NHS. Following approval it became a trading company and the CEO and staff were appointed as employees of Medipex rather than the NHS. An external Chair was appointed following advertisement and the Board was expanded to include external, non NHS members, who now fill 7 of the 14 seats on the Board. During 2004/05 as Medipex developed, other Trusts were invited to become members of the CLG (equivalent to shareholders but without dividends), expanding the membership considerably. The original six Hospital Trusts have seats on the Board and one additional member was elected to represent all other members. From April 2005 membership fees were charged for all Trust members based on a sliding scale depending on the size of the Trust. Key events in the development of Medipex are shown in table 1.

3 **Research Methodology**

An evaluation was undertaken over a period of five years which included the initial start-up period of Medipex. This period was chosen as it was predicted to be long enough to identify the typical level of activity once the process had reached a steady state. However it was recognised that not only would the evaluation be considering the feasibility of commercialising IP emerging from the NHS but also

the viability of a CLG as an organisational model to undertake the activity in the specific environment of the NHS.

The research design was to undertake a prospective analysis of the performance of Medipex using performance metrics which were specified prior to the start of the project, ie before Medipex commenced operation. These metrics were chosen to provide as objective an assessment as possible of the different components of the process of the commercialisation of IP.

Data for the metrics was collected by Medipex staff, and stored on a central database which was continually updated. The data was collected from NHS organisations in the region which ranged from five hospitals at the start of the project to 35 hospitals and other organisations by the end of the project. Details of specific metrics are listed below.

(i) *The number of ideas identified and those which completed different stages of the review and commercialisation process.* The initial data was collected by Medipex staff, not the authors, who were specialist technology transfer managers. In all cases this involved detailed discussion with the originator of the idea. The decision about which projects should proceed to the next stage of the process was made by a panel of independent experts with a wide range of commercial expertise. At each stage of the process the data was stored on the central database.

The unit of data was the number of specific innovative ideas at the early stage of the process. Thus it was not merely patents or research projects being undertaken. Each innovative idea then became one or more projects as it went through the development process. Each project would be associated with a specific commercial output. The second unit of data was therefore the number of projects.

(ii) *The financial information associated with any innovations which had been successfully commercialised.* This included sales, licensing deals, and equity held in spin-out companies. The information was collected and reviewed by the finance committee of Medipex chaired by a management accountant and was the subject of routine financial audit. The use of a CLG imposed a public sector governance discipline which helped the acquisition of rigorous financial information.

(iii) *The number and proportion of NHS organisations which paid to become members of Medipex.* This was used to measure the acceptance of the activity and of Medipex by individual NHS institutions. Organisations were only recorded as being members once they had signed a contract and paid the associated fee.

(iv) *The level of external investment funding which could be accessed to support the development or commercialisation of innovations.* This financial information was recorded and monitored by the finance committee as (ii) above.

In addition to the metrics above, consideration was given about how the external perception of the success or otherwise of Medipex, by the private and other parts of the public sector, might be measured. This information was not the prime focus of the project and was considered as of only secondary importance. The cost effective approach was therefore adopted of entering Medipex and its activity for competitive regional business and innovation awards after three years of operation. This would expose the organisation to external judgement from both the private and other parts of the public sector.

The limitations of the methodology used were recognised but it was felt that the metric based approach adopted, with review of the data by independent groups, minimised the bias that may be inherent in this type of action research. The data for the five year period was analysed by the authors for this publication.

The methodology does not enable us to distinguish between the feasibility of commercialising IP emerging from the NHS from the effectiveness of Medipex as an organisational model to undertake this activity. At the start of the project we had expected that comparable data would have become available from NHS Innovation Hubs in other parts of UK, which used different business models. This would have enabled comparative analysis of Medipex with these different business models to be undertaken. Unfortunately, sufficiently verifiable data was not available from other organisations.

4 Financial model for IP ownership and commercialisation

The principles of ownership and income distribution were set out at the start of the formation of Medipex and the arrangement with all Trusts was the same. However, as there would be many cases

of IP developed jointly with Universities, it was felt important to set up arrangements in principle with all partner Universities. Although it would have been desirable to establish a common approach, the arrangements varied slightly but all were based around a similar framework

- Medipex does not own IP. The ownership remains with the Trust, is transferred to an appropriate partner of the Trust (e.g. its partner University) or assigned to a third party as appropriate.
- Medipex exploits IP that has been identified within the Trusts in the geographic region. Where income is generated it will ensure that it is fairly distributed between the parties concerned. Normally the income would be divided three ways: 30% going to the organisation or organisations commercialising the IP (which could be Medipex) and the balance going to the NHS (with a recommendation that it be divided equitably between the inventor and the Trust).
- As Medipex will receive a proportion of the financial benefit from IP in many cases, this becomes one of the income streams which will sustain it in the long-term.
- If the IP is a result of joint work between an NHS Trust and a University, then the IP split will be divided between the institutions on an agreed basis. If Medipex facilitates such agreements and where it takes the lead it will recoup its costs; this has proved to be a very valuable role for Medipex and has prevented the loss of much IP. If a University takes the lead in exploiting the IP then Medipex recoups any fees through its agreement with the NHS Trust.

On behalf of each NHS Trust, Medipex polices all commercial agreements and collects and distributes any income arising from such agreements thereby ensuring it is delivering an all round service to its NHS members.

5 Results 2003 - 2007

5.1 Staffing and expertise

The approach adopted was to ensure the staffing complement didn't compromise the ability to achieve sustainability; the staffing level was therefore lower than a number of other organisations in other regions of the NHS. The current expertise within Medipex is as follows: (i) CEO who is also actively engaged in technology transfer, (ii) General Manager with operational responsibility, including company secretary, finance and HR, who also has responsibility for non-IP projects e.g. clinical expertise mapping, (iii) three technology transfer experts each with responsibility for a group of Trusts and executive responsibility in spin-out ventures managed by Medipex, an Associate IP Manager, (iv) a marketing/business development person and (v) administrative support. Due to the difficulties in recruiting suitably skilled staff, an in-house training programme was introduced.

5.2 Membership of Medipex

Charging Trusts membership fees in return for provision of IP management services was always part of the business model. After an initial 2 year free membership period a banded fee structure was introduced. Membership of Medipex is open to all 40 NHS bodies in Yorkshire & Humber and currently around 80% have joined. Growth in membership and fees is shown in Figure 2. There is a requirement by the DH for individual Trusts to ensure that their IP is appropriately managed and Medipex not only provided the appropriate mechanism but, in many cases, provided a draft IP policy which could be adopted.

5.3 Education and training

Information and education is provided for staff working in the NHS by Medipex. There is an ongoing need to raise awareness due to the changing workforce but, in the longer term, more of a focus has been given to the provision of information and guidance for staff enquiring about IP. There is a good relationship with RDDirect, the NHS supported telephone help line that provides R&D

advice and RDInfo which is a nationally supported information centre on R&D. Both are run in Leeds as a partnership between the University and the NHS.

5.4 Identification and protection of viable IP

Initially, regular technology scans of potential IP were undertaken as well as developing effective communication links with potential inventors. However, the need for regular scans diminished as Trusts became aware of IP potential. A simplified schematic of the stage and gateway for dealing with IP is illustrated in figure 3. The gateway process initially focuses on ensuring the idea genuinely meets an unmet clinical need and that there is likely to be a market if this particular idea is successful. At each stage a decision is made by NHS and Medipex on whether to proceed further and commit more resources (usually staff time and small amounts of funds for prototypes). The market assessment is commercially and technically focussed, taking into account the sophistication of the technology, the market environment, the care pathway and training issues and who would be prepared to pay. Generally, if the idea still has merit, the outcome is to find a suitable commercial partner to help take the idea forward. The majority of the commercial deals are via a licence agreement; those ideas emanating from clinical practise will usually be licensed to an SME. However, there is a small but growing number of NHS owned spin-out companies being set up in order to exploit the IP opportunity, usually because significant external development funds are needed to help develop the idea to market.

If Medipex believes there is significant potential for exploiting the IP then it will cover the costs for the initial protection in return for a proportion of the financial benefits when they are realised. The commercialisation of IP is pursued as soon as possible after its initial registration, so that the cost of long-term patent protection can be included in the financial discussion with any third party that will be exploiting the IP. If Medipex doesn't consider the IP is exploitable, but where the inventor has a strong personal interest then, by agreement with the employing NHS Trust, the IP may be assigned to the inventor who is then free to take forward their idea using Medipex under a normal commercial arrangement should they wish.

Over 600 ideas have been identified, of which 269 have been taken through the stage and gateway process; further details are summarised in table 2a. After four years of operation, a number of trends are starting to emerge. The figures indicate that around 10% of the projects taken forward result in successful commercialisation of the IP. A further 27% are being actively evaluated and the IP has been enhanced e.g. additional development funds secured, outline patent or trademark applied for. The bulk of the ideas taken forward are medical devices (42%) followed by training materials and software products (28%) and assistive technology (16%). The relatively high figures in 2004 are probably due to residual IP that Medipex was then able to exploit. Thereafter around 140 to 150 new ideas are examined each year. After undergoing a more rigorous market feasibility assessment typically 20 to 30 projects with commercial potential are taken forward, resulting in nine to ten commercial deals brokered per annum. This probably represents a plateau under current arrangements, given the competing pressures on NHS staff time. It is interesting to note that after the initial filtering process there has been a steady but increasing number of viable projects being taken forward to stage two year on year. The most obvious explanation is that as Medipex expertise has developed it is better able to identify and encourage more viable IP to come forward and NHS staff also are beginning to understand how to make use of this expertise.

Informal feedback from the network of Innovation Hubs shows that around 80% of ideas emerging from the NHS resulted from everyday clinical practice rather than from research, i.e. improvements to existing equipment, bespoke software and practical solutions to problems. However, a more in-depth analysis of 60 projects where the IP has been successfully exploited or where Medipex is actively assessing the market potential, indicates nearly 50% of IP emerges from funded research. Furthermore repeating the analysis by potential value rather than by quantity shows that IP arising out of research contributes to more than 90% of the most significant IP and a broadly similar figure is indicated for IP that is jointly owned between a University and NHS (table 2b).

5.5 Filtering of IP involving other partners

All the potentially exploitable IP arising from Trusts is channelled through Medipex with a view to identifying the best agency to exploit it; this includes joint NHS/University owned IP. Issues regarding the percentage split between each partner are usually resolved up front on a 'felt fair' basis with the agreement of the inventors and employers. As important as agreeing the IP share, is the agreement as to which technology transfer organisation (Medipex or University) takes the lead and is able to recover its costs on successful commercialisation before any additional income is distributed.

In certain cases, for example molecular science, it is likely that the University partner would be the best route to manage and exploit the IP. Medipex has developed effective working relationships with regional University technology transfer companies e.g. Biofusion in Sheffield and Techtran in Leeds to ensure that the potential exploitable IP is routed most effectively. In a number of cases the commercialisation of joint NHS and University IP was exploited by Medipex e.g. for medical devices and diagnostics because of its good understanding of the routes to market.

5.6 Commercial Exploitation

Medipex identifies potential commercial partners to whom the IP can be licensed or assigned and then offers its services as negotiator with the commercial organisations to identify the best route to exploitation. Medipex has also worked with a variety of existing agencies to commercialise the IP and, where appropriate, set up spin-out companies to exploit the IP. Initially it had been assumed that the route for the commercialisation of IP would be via licence deals or sales to commercial organisations. However it was found that the formation of a spin-out company was identified as the route to commercialisation more often than we had expected. This was because the innovations were not developed to a near market state sufficiently to generate commercial interest. Medipex was required to obtain approval from the Private Finance Unit (PFU) on behalf of the Secretary of State for Health for the formation of these companies. To date, five new healthcare companies have been set up by Medipex, nearly £2million of investment secured to continue product development and two of the spin outs have commenced trading.

5.7 Non-Commercial Exploitation

One of the unique activities of IP associated with the NHS is the identification and exploitation of IP without any commercial potential but which may have benefits for the NHS, for example addressing hospital acquired infection or reducing patient waiting time. Medipex has monitored such developments and whilst it is not adequately resourced to develop this IP, it has worked with the Service Improvement lead at the hospital level, with the regional Strategic Health Authority and occasionally nationally with Department of Health officials to promote best practise. Occasionally, a more commercial view can be taken if the service is likely to have a major impact and become self sustaining whilst generating and retaining income.

5.8 Commercialisation of the Knowledge Base in NHS

In addition to NHS IP, which can be registered, there are many examples where the specialist knowledge held within the Trusts is of commercial interest for the support of research and innovation. Medipex is actively developing a register of research support facilities and expertise to match them with commercial requirements where appropriate. A number of medical device companies have approached Medipex to broker an appropriate commercial agreement to develop and evaluate new products using the skills and facilities available in a Trust. This works well for all parties since the company has a single point of contact, Medipex, and the Trust has confidence that the arrangement is fair and is managed.

5.9 Associated business activities

A significant amount of training materials, educational content and general software products are assessed each year across the UK. Whilst much of the content is of little or no commercial significance there are an increasing number of ideas that are unique and have invaluable content to

other NHS staff, but because the market may be niche or the output is not in conventional book format, it is difficult to find a publisher/marketing partner. An e-commerce website was created as a solution (www.ennovations.co.uk), providing an outlet for selling and marketing these materials. The website was also found to be a valuable way of marketing and selling other device based innovations, which were thought to be of value to the NHS but for which there was no commercial interest.

Each year Medipex runs an annual innovation competition open to all staff in the NHS working in the Yorkshire region. Commercial sponsorship is obtained to support the costs and an independent panel judges the entries and selects winners in various categories which are announced at an awards ceremony held at a prestigious venue. The event not only serves to identify IP that may otherwise be lost but equally importantly creates positive PR that directly improves staff morale through recognition of their efforts.

5.10 Funding and Investment

The annual turnover for Medipex has increased to nearly £750k. On average between half to two thirds of Medipex's annual budget has been provided by DH and in the early days the balance of funding was from the Office of Science and Innovation funds. Continued core funding support from DH is essential in order to ensure the IP activities become embedded within NHS Trusts and a sufficient financially robust IP pipeline is established that would support Medipex and demonstrate added value to NHS Trust members.

In the years since trading activities commenced, additional income has been brought in as a direct consequence of its activities and currently accounts for 30% of the annual budget. This figure is forecast to increase slowly with financial break even (100% turnover secured through income derived from trading activity) by 2014. This assumes that Medipex does not increase its support for development of non-commercial innovations of value only to the NHS; at present these account for less than 10% of Medipex activity.

Medipex has developed and managed a Proof of Concept (PoC) fund with a view to creating an evergreen fund. This has proved essential in developing ideas to a stage which ensures commercial interest. Proof of concept funding is offered if innovations (i) have a realistic prospect of attracting a commercial partner within 12 months of the commitment of funds; (ii) would, if successful, result in products appearing on the market within 18 months, (iii) have a realistic prospect of generating sales that result in products with annual invoiced sales in excess of ten times the original proof of concept funding and (iv) have the potential to make a return to the fund on the basis of an average royalty of 2.5% on the resulting invoiced sales. The Proof of Concept funds have not been in operation for long enough to have established a return on investment yet. A total of £233K has been invested in 27 projects (£1K to £50K) and three or four are likely to generate significant revenues within the next five years.

Follow-on funding in excess of £50K and less than £250K has proven very difficult to obtain from conventional sources unless the risk versus return can be shown to be acceptable, but in the case where the technology is breakthrough or particularly novel this can be virtually impossible to quantify. A noteworthy pipeline relationship has been established with a London based private equity investor, Exomedica, that specialises in medical technology and devices, which will make available £1 million of early stage proof of concept funding (£50k to £150k per innovation) in return for first right of refusal.

6 Discussion and Conclusion

The financial framework of an organisation such as Medipex is complex, dealing, as it does, at the interface between the private and public sectors which is further compounded by the need to secure funding for both itself and its customers from governmental and private investors. Medipex appears to be a good model for technology transfer and commercialisation in the NHS, successfully combining private sector expertise and public sector infrastructure. This is in no small part due to its focus on commercial exploitation and developing the skills necessary to deliver this service to its members.

Comparison against other technology transfer organisations in the public and private sector indicates that unless there is a sufficient critical mass then technology transfer can be very uncertain. In addition the model of a CLG, independent from a single organisation, enabled Medipex to realise the benefits of private sector governance whilst retaining the trust and support of public sector organisations.

It had always been recognised that there would be a requirement to respond to the concerns and expectations of both private and public organisations whilst being successful in transferring the technology from the public to the private sector. Results suggest that this has been achieved to a significant degree.

- The number and value of commercial deals achieved per annum ranks Medipex as one of the best performing hubs size for size when compared to the others.
- The value that the NHS places on Medipex is reflected in the high proportion of organisations which have been willing to pay to become members. This has led to it becoming DH guidance for all Regional Innovation Hubs.
- Medipex was able to maintain a focus on ideas and innovations which were not taken up commercially but which were perceived to have a potential value to the NHS. At the start of the project it had been expected that another part of the NHS would assume responsibility for progressing these ideas but this did not happen. The solution of developing an e-commerce website has proven successful as indicated by the fact that most of the national Hubs utilise its services, as do some commercial companies.
- A significant level of external investment funding has been raised from both the public sector, which funded a proportion of the proof of concept fund, and the private sector, which also supports part of the proof of concept fund and also provides equity investment.
- Medipex submitted itself to external scrutiny when it entered for the Regional Young Company of the Year award in 2006 and for a Regional Innovation Champion award in 2008. It was successful on both occasions.

A challenge from its inception for Medipex was the competing and sometimes excessive expectations of the national DH. In addition, though the DH provides a significant level of investment, it does not have direct responsibility for the development of innovations, which occurs at Hospital Trust level, nor does it benefit directly from any successes. On the one hand there is an expectation from Trusts that funding will be available from DH to facilitate the commercialisation of ideas, but that the benefits should accrue to the Trusts themselves. On the other hand there is the belief by DH that there is a large amount of unrealised commercial potential from innovations in Trusts which should generate significant income and reduce their budgetary pressures. Both views have legitimacy but there may be an over optimistic expectation from the DH with regard to the timeframe of the realisation of the income potential. In addition, from the start, it was our view that to deliver improved healthcare effectively, it would require the best ideas to be turned into commercial products in order to achieve wide scale adoption.

Changing cultural attitudes within hospitals has required particular attention. Individual Trusts have an interest in 'non-commercially viable' IP that could benefit the NHS directly, for example reduced waiting times. This is the area which inherently most appeals to NHS staff; thus a large proportion of ideas submitted to Medipex emerge from this area, creating substantial opportunity costs for Medipex and raising expectations which have to be managed. Medipex can identify ideas which may be in this category but, unlike potentially commercial IP, it cannot progress the ideas.

So it is within this environment that we envisage that the following financial framework will be required. There will be a need for continued funding from the public sector to support and maintain the culture change required and enable the NHS and individual Trusts to benefit in the future. There will be increasing income from commercialisation opportunities leading to sustainability of this business stream. However the period of time before sustainability can be achieved is likely to be ten years, longer than may have been envisaged by the NHS, but not unexpected for those who have worked in the University technology transfer sector. The need to attract relatively low level external proof of concept funding for potential innovations is likely to continue, which is a somewhat unusual

situation for an organisation as large as the NHS. Continued support from the DH will be required if it wishes innovations to be identified and developed which would support its core business.

A number of factors have emerged which were not initially appreciated. The first is associated with the nature of the innovations. So far there has been a steady deal flow; for Medipex, working with 37 NHS organisations, the average annual deal flow looks to be about ten commercial deals per annum (mainly license deals) with the likelihood that one or two of these may result in new spin-out companies. The accepted wisdom in the DH for many years has been that the large majority of innovations will emerge from service users rather than from research. It has been shown in this study that this may be the case in terms of innovations proposed; however in terms of eventual commercial value the output from research is much greater than many people had predicted.

The second factor is the continuing funding gap for early stage development. Medipex has had to assume responsibility for obtaining PoC funding as well as appropriate 'accelerator funding' to fast track projects that look promising but are still some considerable way off the market i.e. range £50K to £150K. The type of pipeline arrangement with Exomedica has now resolved this issue to a large extent and it provides a level of confidence that projects can be moved forwards and with the growing expertise of Medipex staff the rewards become more likely.

The third factor is that a need has been identified for a number of supporting or complimentary activities which include (i) the provision of management, accounting, and premises management for incubating NHS spin outs, (ii) IP exploitation consultancy services to external organisations and (iii) assistance to medical technology SME's looking to collaborate with NHS.

The fourth factor was the relative dearth of staff with the appropriate expertise. This has been resolved by the development of a training programme but such an approach is a considerable financial burden for relatively small organisations.

Though the model of a company limited by guarantee appears an effective mechanism for technology transfer and commercialisation for a large public sector health organisation such as the NHS, there are a number of implications from the results which are worthy of consideration.

When dealing with a large public sector organisation such as the NHS, it was found essential to have individuals within Medipex who had both experience of the NHS culture and expertise in IP commercialisation. The awareness of NHS cultural issues ensured that Medipex rapidly gained the confidence of individual NHS organisation. It became apparent that the achievement of this, before the commencement of any financial discussions and negotiations, was invaluable.

Our results show the importance of decoupling the commercialisation of IP from the NHS from direct management by individual NHS organisations. The value of incorporating a private sector governance approach has led Medipex to successes not initially achieved by other IP Hubs. It has also facilitated a balanced engagement with the University sector.

The time to achieve sustainability is predicted to be about ten years, longer than many public sector organisations would expect. In addition, the ability to achieve sustainability is compromised by the expectation and requirement of the public sector organisation for Medipex to undertake activities which do not contribute to financial sustainability; particularly the assumed responsibility for internal IP management and the desire for support for non-commercially viable IP of possible value to the NHS.

A restriction imposed at the inception of IP Hubs, was that the NHS retains ownership of any IP. As a consequence it was not possible to test a business model in which Medipex owned the IP emerging from the NHS. It would be valuable to test a model where the IP was owned by an external organisation (such as Medipex) which may then be able to generate larger amounts of investment funding to support the early development of ideas in return for a share in the IP. This could result in an increase in IP emerging from the NHS. Currently, though the NHS owns the IP, it does not invest sufficiently in its development.

There was an expectation from the NHS that the majority of IP would emerge from clinical service experience rather than from research and this affected their policy toward the IP Hubs. However our results indicated that though the majority of initial ideas come from clinical service experience, the commercial deals of potentially high value came from research based innovations.

On a more general level, the medical technology sector is now seen as a viable market by investors. There are over 115 life science companies listed in the UK and generally IPO's (i.e. raising finance through public subscription of shares) have been well supported. However, most of these are capitalised at much less than £20 million and whilst the sector may be relatively immature there is a clear need to build further on the strong science and clinical base and in particular to create a better environment for small companies to operate within the UK healthcare sector.

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References

- Baker, J (1999) 'Creating knowledge creating wealth - realising the economic potential of public sector research establishments', *HM Treasury*.
- Bozeman, B (2000) 'Technology transfer and public policy: a review of research and theory', *Research Policy*, Vol. 29, Issues 4-5, pp. 627-655.
- DH (2002) 'The NHS as an innovative organisation: a framework and guidance on the management of intellectual property', *UK Department of Health*, Report 29030, pp. 1-82.
- Markman, G.D., Phan, P.H., Balkin, D.B. and Gianiodis, P.T. (2005) 'Entrepreneurship and university-based technology transfer', *Journal of Business Venturing*, Vol. 20, Issue 2, pp.241-263.
- Savory, C. (2006) 'Does the UTTO model of technological transfer fit public sector healthcare services', *International Journal of Innovation and Technological Management*, Vol. 3, No. 2, pp. 171-187.
- Shergold, M and Grant, J. (2006) 'Evolution of the R&D strategy of the Department of Health', *UK Department of Health*, Report PM-2001, pp. 1-35.
- Smith, M.A. (1996) 'Health technology assessment and the NHS R&D initiative', *Journal of Medical Engineering & Technology*, Vol. 20, No. 6, pp.192-195.

Figure 1 Region covered by Medipex. The larger dots indicate the Hospital Trusts who were members of the consortium at the formation of Medipex. The smaller dots indicate Trusts who have subsequently become members.

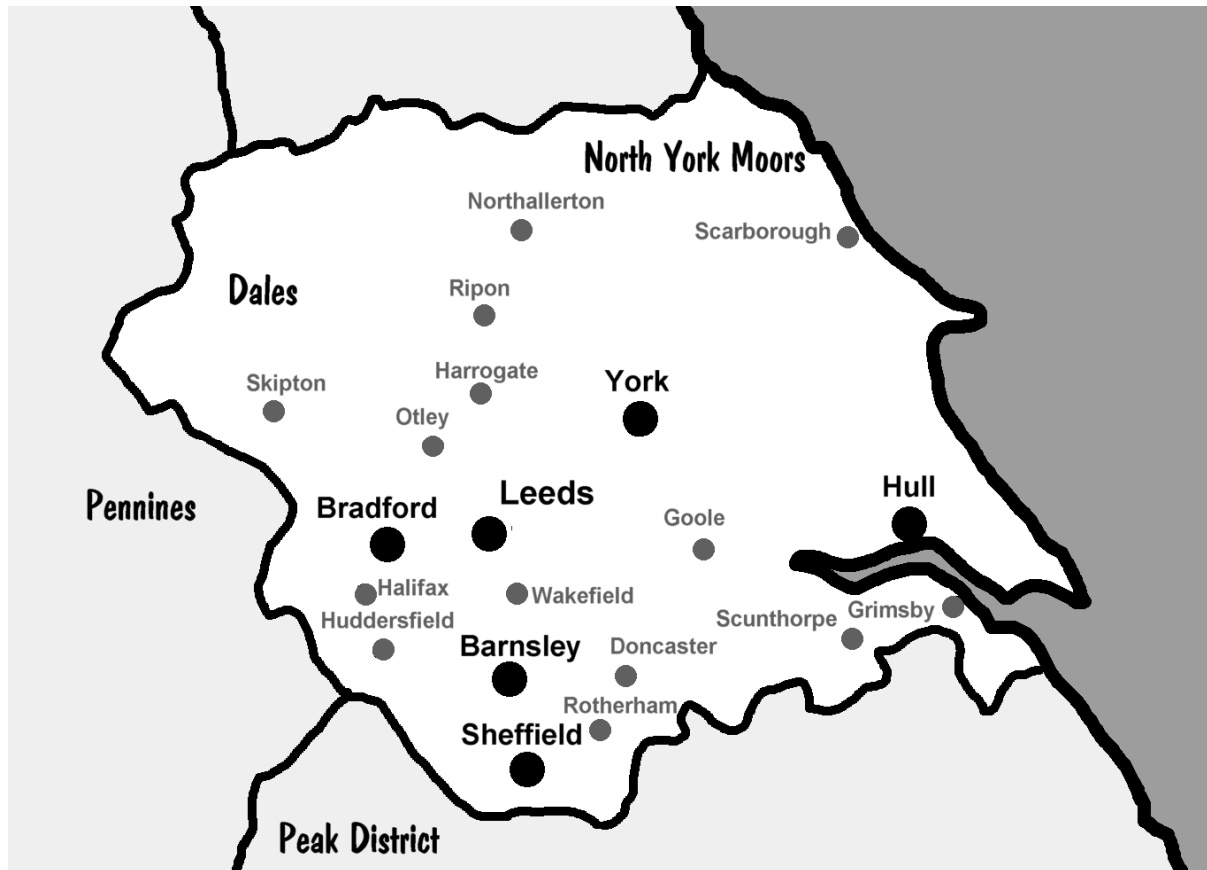


Figure 2 Growth in the number of hospital and primary care Trusts who are members of Medipex and the total annum membership fee income

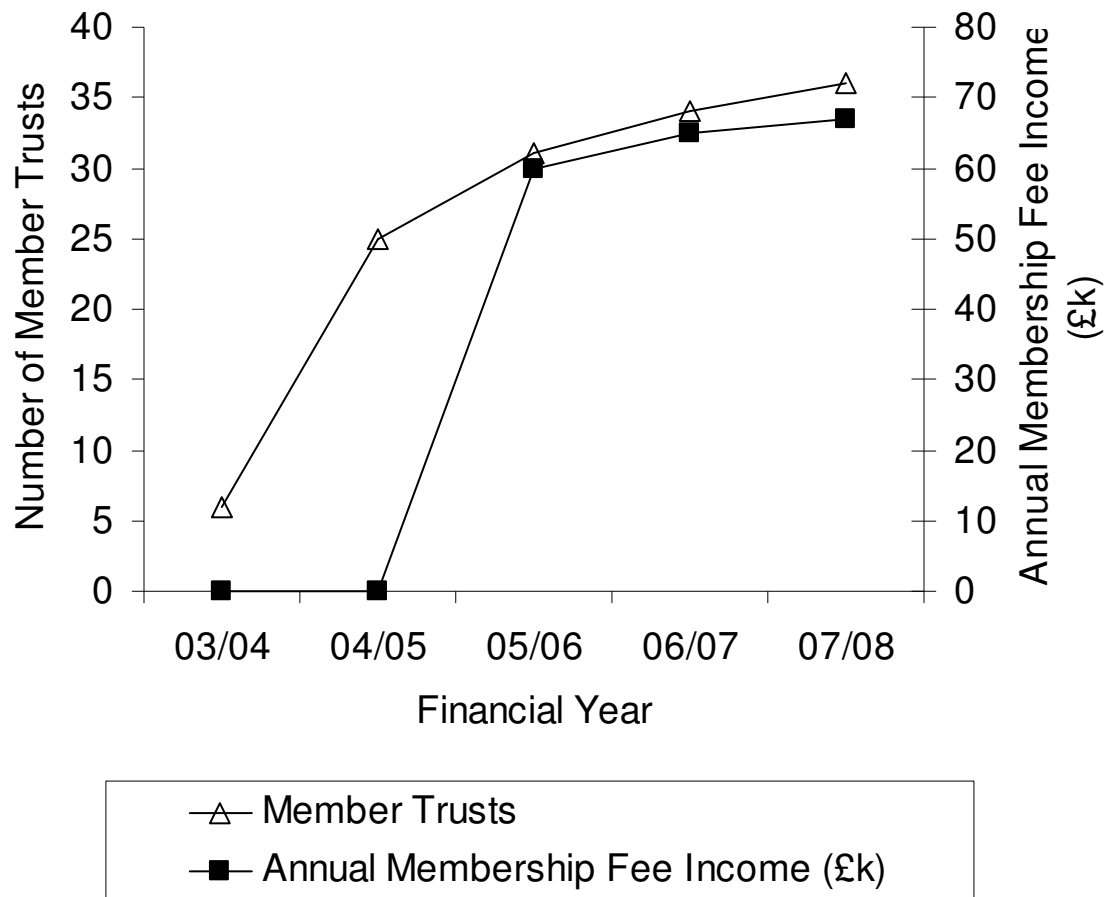


Figure 3 IP stage and gateway flow chart

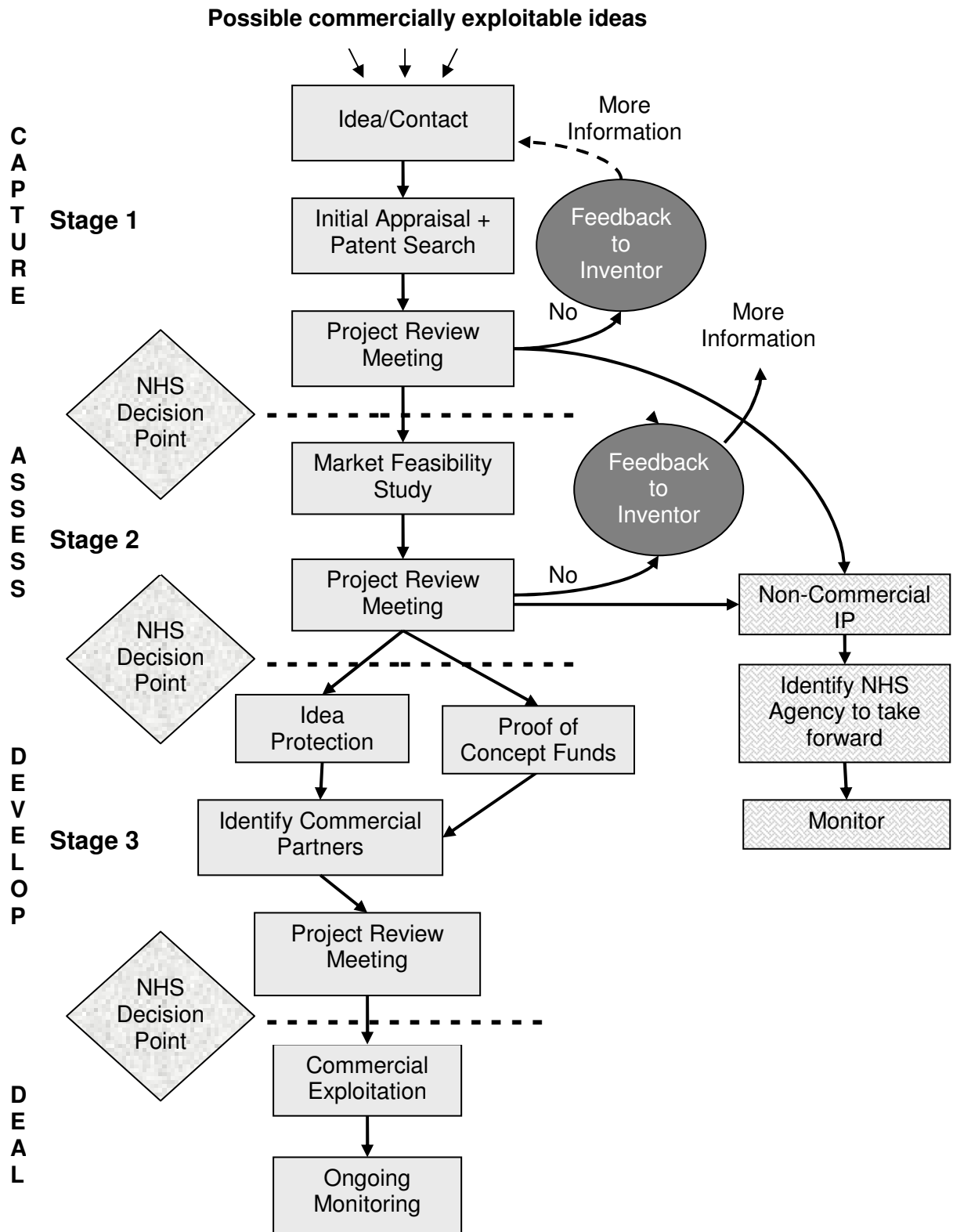


Table 1 Key milestones

July 2001	Business models explored, consortium formed and initial bid for PSRE round 1 funding submitted
July 2002	PSRE 1 funding obtained
July 2003	Bid for PSRE 2 funding
Mar to June 2004	Initial staff recruited
Mar 2004	First board meeting, Successful PSRE 2 bid
April 2004	Membership opened up to all NHS in region
Dec 2004	25 NHS Trusts members
April 2005	Membership fee introduced
Dec 2005	First licence agreement
Mar 2006	First royalty income (\$50k licence deal) First spin out company
Jun 2006	Obtained first VC funding
Oct 2006	Membership at 80% of Trusts in Region
Nov 2006	Selected as Young Company of the Year in Yorkshire
Dec 2006	Obtained £1 million pipeline investment deal

Table 2a IP dealt with by Medipex. The stages mentioned refer to figure 2

	2004	2005	2006	2007	Total
Total number of ideas identified	211	158	144	143	656
Ideas taken forward into the stage and gateway process	50	44	62	113	269
Projects considered potentially of commercial value (Completed Stage 1)	23	27	45	100	195
Projects which are being actively pursued commercially (Completed Stage 2)	27	16	17	13*	73
Successful commercialisation of project (Completed Stage 3)	2	7	9	9*	27

* These figures will increase as the process continues during 2008

Table 2b Estimated market size of the bottom row of table 2a.

Prospective Market Size £m	< £1 m	£1m - £10m	£10m - £100m	>£100m
Projects arising from R&D	5	13	4	2
Projects arising from service improvements	15	4	0	0