IP Management in the National Health Service in England

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ABSTRACT

This chapter summarizes how intellectual property (IP) arising from within the National Health Service in England is managed within the context of a national framework for managing IP from public sector research in the United Kingdom. Describing how the policy framework was developed and how National Health Service organizations were set up to manage IP, this chapter also charts progress in the administration of health R&D and the management of IP and summarizes how IP management complements R&D in the National Health Service.

1. INTRODUCTION TO THE NATIONAL HEALTH SERVICE

The National Health Service (NHS) is England's national healthcare provider. It is managed by a government department, the Department of Health, under the secretary of state for health. Similar arrangements exist for the provision of health services in Scotland, Wales, and Northern Ireland. The healthcare system is almost entirely administered and operated within the public sector—free at the point of use—with the minimal involvement of a small private sector. The National Health Service in England is one of the world's largest employers, with over 100,000 people currently employed.

Healthcare provision is divided into services available in the home and community (such as general medicine, maternity services, home health care, and prescriptions), and services available through hospitals. Healthcare provision is managed by a number of NHS trusts, self-governing organizations funded by the Department of Health. In 2006/2007 allocations were made to 176 acute trusts (consisting mainly of traditional hospitals), 31 ambulance trusts, 82 mental health trusts, and 303 primary care trusts. There are also nine care trusts, which are new organizations that provide combined health and social care. The primary care trusts are the conduit for the bulk of the national budget for all health provision. They allocate funds to other trusts according to needs and priorities. The trusts do not make a profit, although they are required to break even, and must deliver high-quality services, using the resources provided, based on a series of targets. Organizations are managed across nine regional areas: north, northwest, Yorkshire & Humberside, east Midlands, west Midlands, east, London, southeast, and southwest.

2. R&D WITHIN THE NATIONAL HEALTH SERVICE

Most hospitals engage in research, and clinicians of all disciplines participate in many thousands of projects of differing sizes and complexity. Most research takes place in the teaching hospitals, which train mainly doctors. There are around 20

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major medical schools in England, each affiliated with several NHS trusts.

Until 1992, this research was unmanaged. Universities and other research organizations, including commercial organizations, used the NHS infrastructure essentially as a free good to meet their requirements. But when the NHS R&D program began in 1992, the NHS became the only national health service to have its own R&D program. Its initial objectives were to:

- identify research questions that needed to be answered
- undertake research to answer the questions
- implement the answers to improve healthcare.

The resulting program based on these objectives has contributed significantly to the development of evidence-based healthcare internationally.

This is only part of the program. In 1994, an R&D budget (a levy on the total healthcare budget) was established by collecting together all the declared R&D expenditures of every hospital (R&D support funding). A budget for the NHS R&D program was also added. R&D support funding was divided into two budget headings: a budget to support noncommercial research done by others in receipt of their own external funding, and a budget to support research. The first budget meets all NHS costs for externally funded programs in universities and other agreed-upon research partners (research councils, medical charities, the Department of Health, and other government departments). The second budget only supports programs of the required quality. The NHS R&D program has now been extended from its original objectives to straddle such programs as Health Technology Assessment, Genetics Knowledge Parks, Research Networks, the Cochrane Collaboration and Systemic Reviews, and the expansion of a clinical research facility to support clinical trials. In 2004/2005, the total NHS R&D budget was UK£604 million, made up of UK£487 million for R&D support funding and UK£117 million for the NHS R&D program. Details of the whole program and how it is developing (including plans to bring together the NHS budget and the Medical Research Council budget within a new National Institute for Health Research) can be found on the Department of Health Web site.[1]

The research governance framework for carrying out research in the NHS[2] requires all those undertaking research to understand the importance of IP in their research and to take steps to identify and protect valuable IP.

3. IP IN THE NATIONAL HEALTH SERVICE: THE EARLY STAGES

3.1 *The nature of NHS IP*

NHS IP is generated in two ways:

- through R&D programs carried out by NHS researchers
- through the delivery and management of healthcare by NHS employees

The NHS carries out little fundamental noncommercial medical research. This is normally led by universities whose funding is provided principally by research councils and charities, but often with NHS staff as collaborators (and funded by R&D support funding). There is a small (but growing) band of NHS employees employed principally to do research. Much R&D expenditure in the NHS supports others, for example, university researchers, and IP arising from this work is often generated jointly with the research partner. Even though about one in three academic papers in bioscience has an NHS author, the R&D programs in which NHS researchers participate are not the major source of NHS IP. The NHS employs around 100,000 people who can generate IP in their day-to-day jobs, and their potential to come up with ideas for new products, processes, and treatments is significant. This potential was the principle driver for developing the program to manage IP in the NHS.

3.2 *The development of a policy framework*

The development of a policy framework to manage IP in the NHS began in 1998 with the appointment of the author of this chapter as NHS

intellectual property advisor. R&D issues were addressed first. A health service circular (the method of publishing policy at that time) entitled A Policy Framework for the Management of Intellectual Property within the NHS arising from Research and Development[3] was published in 1998. It set out, for the first time, the principles of IP management. The circular was supported by two additional publications:

- Handling Innovation and other Intellectual Property: A Guide for NHS Researchers[4]
- The Management of Intellectual Property and Related Matters: An Introductory Handbook for R&D Managers and Advisers in NHS Trusts and Independent Providers of NHS Services[5]

The guide for researchers was designed to inform researchers about what constitutes IP, how to recognize it, and what to do. The handbook was for R&D managers (generally each research-active trust has an R&D manager), but not for IP practitioners.

The policy framework had the following basic principles:

- IP generated in research belongs to the organization employing the researcher
- if the IP has commercial value, it should be protected and commercialized by a suitable organization on behalf of the owner
- income generated by commercialization should be shared between the inventor, the owner organization, and the commercializing organization

These principles were foreign to the NHS because they raised the possibility that one NHS organization could retain income generated by the commercialization of IP and not share it with fellow organizations. Although these principles were agreed to and the framework was published, it was recognized that it would be more difficult to get others to sign up for these principles outside an R&D context.

In 1998, it was too early to extend the policy to IP arising from all sources, particularly from patient care. Moreover, the set-up and use of companies by NHS organizations to aid commercialization was specifically not allowed at this time, although this restriction was seen as an impediment to commercialization; because NHS owners of IP could not have a stake in spinout companies, collaborative work with universities would be inhibited.

At the time that the NHS was publishing its policy framework for IP arising from R&D, the national climate for innovation was changing and the government was determined that the public sector should develop a knowledge-based economy that would recognize IP, treat it as a national asset, and translate it into the benefits of jobs and prosperity. The treasury and the Department of Trade and Industry published a series of documents that changed the IP landscape across the entire public sector.

4. PUBLIC SECTOR IP IN THE UNITED KINGDOM

In 1985, U.K. universities had been given freedom to own and commercialize IP arising from their research funded by research councils. If universities wanted this freedom, they had to set up approved management systems. Almost all of them now have approved systems, and almost all are based on the principle of ownership by the university, an obligation to commercialize (or to give back to the researcher), and benefit sharing with the researcher.

Research is carried out in the United Kingdom not only by universities but also by a number of public sector research establishments (PSREs). In 1999, PSREs and NHS trusts spent UK£2.2 billion out of a total of UK£6.75 billion of research funding. Apart from the Institutes of the Medical Research Council, there was little history of government laboratories managing IP outputs. To try to change this position, the treasury set up a task force, which in 1999 published the Baker Report.[6] It made a series of far-reaching proposals that were accepted by the government,[7] which required all PSREs, many employing civil servants, to have systems in place to identify and commercialize IP of value. Moreover, the transfer of research outputs to benefit the wider national economy had to be part of a PSRE's mission.

The government confirmed that IP should be owned by the PSRE, which was usually the most appropriate organization (rather than its sponsoring department) to transfer the benefit to the national good. It was also generally recognized that income derived from this activity should be retained by the PSRE and not reclaimed by the sponsor. It confirmed that researchers, many of whom were civil servants, should be allowed to share in the income generated, and that when commercialization is achieved through the setting up of a spinout company, the researchers could have an equity stake. An initial fund of UK£10 million, against which PSREs could bid, was made available to allow PSREs to set up commercialization offices and increase their capacity to manage IP outputs.

The Baker report and the government response to it meant that all research outputs from public sector research would be managed under a common policy (mirroring that of universities). This policy fundamentally changed the position of researchers and their organizations. In addition, guidelines for the treatment of IP in government research contracts were published by the U.K. Patent Office.[8] These were all major changes.

5. DEVELOPMENT OF THE NHS FRAMEWORK

The work behind the development of the Baker report paralleled and in part informed NHS developments. The ability of an NHS trust to retain income generated by the commercialization of IP was used as a precedent by the treasury task force, and the support for spinout activity in PSREs led to renewed efforts to allow NHS trusts this freedom. The NHS trusts had by now been categorized as PSREs and were eligible to participate in funding schemes, particularly the fund that had been made available to set up IP management offices.

Despite the publication of the Baker Report, it was not until 2002 that the Department of Health was able to publish a policy document covering the full range of NHS outputs. This took nearly three years of intense effort. By 2002 it was no longer possible to prescribe policy; it had to be guidance against which progress (and compliance) could be measured. Aimed at providing a common framework for all NHS organizations, the document was called *The NHS as an innovative Organization: A Framework and Guidance on the Management of Intellectual Property in the NHS*.[9]

The title refers to the NHS as an innovative organization, which reflects the fact that by 2002 innovation was recognized by the Department of Health at the highest level as an important part of the work of the NHS. This was largely the result of the new government agenda for supporting innovation within a knowledge-based economy.

The content of the framework and guidance covers three main areas:

1. The management framework
2. Employment and ownership issues for organizations and employees
3. Partnership in IP management with universities and other research funders

Each area had complex issues to be resolved; we explain below how the most important of these were overcome. The content itself was developed by closely working with Department of Health commercial lawyers, and although the document is more legalistic than might have been imagined initially, it was vital to ensure that the secretary of state for health was protected from any legal challenge in this frequently contentious area.

5.1 *Extension to the existing policy framework for R&D*

NHS IP can arise from NHS R&D and from the delivery of patient care by all those employed by the NHS. The 1998 circular sets forth the responsibility of NHS organizations receiving R&D funding to identify IP arising from research, but NHS organizations were not responsible for systematically capturing IP associated with the delivery of patient care. This situation remains the same. However, trusts are expected to have access to a management structure (such as that described in section 5.7), so that when any IP is found employees have a place to go for expert advice. The position in the Framework and Guidance is that outputs from patient care should be man-

aged in the same way as those from R&D. The Framework and Guidance recognizes that not all outputs will have a commercial endpoint and that some (indeed the majority) should be treated as opportunities to change practices by freely disseminating them across the NHS.

The statutory purpose of commercializing IP in the NHS (captured in the 1977 and 1990 NHS acts) is to make more income available for the health service. When an invention is exploited successfully and new products of commercial value are produced and sold, income will be generated (and shared with inventors). However, when the IP relates to a change of practice (usually covered by copyright), income generation is unusual. Nonetheless, because costs could be saved, it was agreed eventually that cost savings could be treated as income generation and so satisfy the statutory requirement.

5.2 *Income retention by the trust following commercialization*

Sharing income with inventors is a fundamental part of IP management within the public sector in the United Kingdom, and the principle was readily accepted and supported by health ministers and NHS leaders. However, it was more difficult to get the wording of the Framework and Guidance accepted by those charged with managing NHS finances. This is because it ran counter to a fundamental tenet of the NHS: any surplus income should be shared with other NHS organizations. In the end, it was agreed that surplus income arising from the commercialization of IP after paying all costs, for example, inventors, could be retained by the trust and used at the discretion of the trust to improve healthcare. It could be used to improve a service but not, for example, to build car parks. A retention limit of 0.2% of the trust turnover was set before it was necessary to bring a successful commercialization to the attention of those providing funding to the trust. In practice this meant that, unless there was a blockbuster invention, the principle had been accepted.

5.3 *Ownership of NHS IP*

Under U.K. law, IP (patents, copyright, trademarks, design rights, and know-how) generated by an employee in the course of employment or normal duties belongs to the employer unless the employer and employee have agreed otherwise. The latter was rare because in 2002 few employees had contracts that addressed IP.

However, for patented inventions the law gives additional conditions that must be met in order for the employer to own the rights. Not only must the invention be made in the course of normal duties, but it must also have been reasonably expected that an invention would result from such duties. For example, this would be reasonably expected for an employee engaged in R&D, but it could be doubtful for a surgeon performing an operation who suddenly realized how it could be done better.

The view contained in the Framework and Guidance is that should a surgeon (or any other employee) invent something during normal duties that requires a patent and needs development and testing before it can be used on patients, then the patent should be assigned to the employer to manage (as for all other IP) should the inventor want to use NHS resources to develop the invention. There is no requirement to assign the patent unless NHS resources are used, but since almost all such inventions would require development, and since the NHS would provide the most convenient test bed, the need to argue ownership through potentially costly legal procedures would be minimized. If an employee chose not to assign the invention to the employer, it would need to be developed, perhaps in the garden shed, without using NHS resources. Such considerations become redundant if all NHS employees have appropriate conditions in their employment contracts.

5.4 *Employment conditions*

If a trust has employment conditions that set out the responsibilities of the employer and the employee on all aspects of IP, then questions of ownership generally disappear and the focus can be on using the IP.

The Framework and Guidance include model employment contracts and a model entry to a staff handbook or similar document. It also considers staff appointed jointly with universities or

other organizations and staff who combine NHS duties with private practice.

During his tenure as NHS intellectual property advisor, the author encountered examples of physicians who had made an invention, used NHS resources to develop it without informing the employer, and then claimed ownership when challenged because it was developed in private practice. In one case a new device had been patented and licensed to a U.S. medical device company without the knowledge of the employer. It was brought back into the ownership of the trust because it clearly arose from a research program.

A number of factors, foremost among them the high turnover of human resources staff and the lack of IP experience in the NHS, made it difficult and time consuming to clear this part of the Framework and Guidance through the Department of Health. Clearance was eventually given to the content when it was realized that only guidance was being given, so trusts could choose not to follow the guidance if they wished. In reality trusts are pragmatic and follow the guidance because to do otherwise would involve them in a great deal of legal work.

5.5 *Partnership with universities and other NHS research partners*

The NHS undertakes research jointly with universities and other research partners, such as charities and research councils. IP arises from this joint work, and ownership might not be clear. Before 1998, the NHS had no structure to recognize or manage IP, and almost nobody in the NHS was in a position to do anything about it. Almost by default, ownership was claimed by the research partner. There were many examples where inventions were realized through joint work but where no benefit came to the NHS.

Universities agreed in 2002 to a statement of partnership, which specified that when IP is generated by joint R&D between NHS trusts and universities (for example, by individuals holding a joint appointment), or where both the NHS and the university are partners in the research, then the organizations together should decide:

- which organization owns the IP
- which organization is to manage the IP and how costs are to be met
- how any benefit is to be shared after paying all costs (for example, inventors)

These arrangements are for research performed jointly, even if the inventor is solely employed by one organization. Frequently, the other organization contributes to developing the IP, and so by agreement it can be a beneficiary. The statement of partnership expected that a collaborating university and NHS trust would have similar revenue-sharing agreements with their inventors so that inventors from different organizations would be rewarded in a similar way when their invention generated income.

There is no rule that determines how benefits are to be shared, but current recommended practice starts with equal shares for both parties. If the parties agree otherwise, it is adapted. In practice, university and NHS bodies are moving ever closer in their ways of working—the 50:50 sharing model is becoming the norm, which is far removed from the previous 100:0 model!

5.6 *Spinout companies: The Health and Social Care Act 2001*

Publication of the government response to the Baker Report opened the way for a bill to be placed before parliament in 2001 that allowed NHS organizations (NHS trusts, primary care trusts, and so on) to set up, participate, and invest in companies to generate income. The scope was intended to be wider than just IP; in fact, the legislation does not even mention IP or spinout companies.[10] The advantage of a wider provision became clear when some of the earliest uses of the legislation were for companies that had nothing at all to do with IP.

If they are badly set up, the use of spinout companies carries inherent risk. NHS organizations are generally not free to set up companies without a business plan authorized by the Department of Health. The business plan must comply with Directions (which are legally binding) contained within the Framework and Guidance. This essentially protects the secretary of state for health against unnecessary risk, and

it has meant that the Department of Health (like other government departments) has had to develop expertise in a new area of activity.

The Framework and Guidance includes detailed guidance to trusts and employees on how companies should be established, the role of the trust, and the position of employees as directors or shareholders. The content follows national guidance provided in the government response to the Baker Report.

5.7 *Management of IP in the NHS*

5.7.1 *The concept*

The Baker Report recommended that PSREs should establish management systems to deal with their IP. But how were the outputs from the acute trusts, the ambulance trusts, the mental health trusts, the care trusts, and the primary care trusts—a total of 601 organizations in 2006—to be dealt with? Although research outputs might be expected to concentrate around teaching hospitals and their partner universities, no such assumption could be made for innovations in patient care from doctors, nurses, scientists, technicians, and so on. It was clearly not cost effective or appropriate in terms of likely business to locate a management organization in each of the trusts.

Extending the scope of university technology transfer offices was rejected because their interest would be primarily in research-based innovations; patient-care-led innovations were likely to be lost. Universities were already being stretched by the government innovation agenda.

The agreed management solution was for nine regionally based NHS innovations hubs. These map on to the regional government structures (regional development agencies) in England. Each hub covers on average 60–70 organizations. Section six describes their operation in more detail.

5.7.2 *The hub as an organization*

A hub is either an unincorporated association of NHS bodies or a company limited by guarantee. It has a management board that decides structures and hires its own employees. In an unincorporated association, the employees are NHS employees; in a company limited by guarantee they are employed outside the NHS. Currently, the hubs are split approximately equally between the two models. Generally, the hubs have "branch offices" that reflect the region's different geographies. The London hub, for example, has one central office with outposts located close to the five principal teaching hospitals. The southwest hub, which covers one of the largest geographical regions, relies more on electronic communication than direct contact.

5.8 *License agreements*

The Framework and Guidance includes terms to be used in license agreements with commercial partners. It also includes, for developing countries, a specific appendix taken from MIHR (Centre for the Management of Intellectual Property in Health R&D) documentation that was produced for The Rockefeller Foundation in November 2001.

In the terms for license agreements, the Framework and Guidance recognizes that most commercializable items of NHS IP will have an international market and that licenses will cover manufacture and sale in more than one country. The Framework and Guidance states that license agreements should seek to include terms that are likely to give patients in developing countries access to products at reasonable cost.

As stated earlier there was some dispute as to whether all NHS trusts should benefit from an invention made by another trust, particularly whether products arising from the invention should be royalty free to the NHS. The Framework and Guidance says that those negotiating the license agreement (the NHS innovations hub or another body) should seek to include preferred terms for sales to other NHS organizations. Essentially, however, the main way for a trust to benefit is through developing its own inventions.

5.9 *Independent providers of health services within the NHS*

Some health professionals (such as general practitioners, dentists, and pharmacists) are not NHS employees but work under contract with a primary care trust. Some of these professionals generate

IP through NHS research and others through their services. The framework and guidance recognizes that the NHS is unlikely to own IP outside R&D, but it offers these professionals the services of the NHS hubs under the same terms and conditions as NHS employees, if they assign the IP to the primary care trust.

6. THE WORK OF THE NHS INNOVATIONS HUBS

IP management is a complex task and has not been a core business for the NHS. Ideas for new technologies (new or improved devices, for example) need to be protected, often by filing a patent application. Converting ideas into new products—and rejecting unsuitable ideas—require specialist skills, and the NHS innovations hubs have been set up to provide these services.

The first hub in the northwest began its operation in 2001, which was followed by the other eight. The last hub was only recently established in the southwest.

A driving force for their creation was the UK£10 million PSRE fund set up by the Department of Trade and Industry against which PSREs could bid. In the first round of funding, UK£6 million was provided to create capacity for IP management in the public sector, and UK£4 million for setting up seed funds. NHS trusts could apply, and bids for funding to create capacity were made from all regions through a lead trust. The fund was oversubscribed, but many NHS bids were successful in the first round of funding, receiving about one half of the total available funding. There have been two further rounds, and all hubs have now received funding from this source. This adds to core funding provided by the Department of Health; initially this was UK£2 million per year but has since increased.

The hubs are developing their operation in close partnership with the nine regional development agencies, government organizations set up to stimulate and support local business. Several of the regional development agencies provide additional funding for the hubs in the expectation that they will be the source of new products, processes, and businesses in their region.

The services that a hub provides include:

- identifying IP through clinics and similar activities
- providing training for NHS employees in the importance and understanding of IP
- evaluating IP and initiating additional R&D to produce evidence of clinical application
- protecting IP
- commissioning the production of prototypes
- advising on and exploiting IP through licensing or setting up of companies
- collaborating with universities and other third parties in the exploitation of IP generated jointly with trusts

Each hub establishes its own networks and determines its mode of operation. A national network, the IP Forum, meets monthly or every two months. Most hubs charge a membership fee to their member organizations, and a large majority of the trusts have chosen to join their hub. Hub networks usually partner with networks of R&D managers. Geography plays its part, but members of a hub typically have much in common. They extend their scope through establishing a "product champion" in a member trust who acts as the first contact point for the hub. Currently, hubs employ five to 20 people, depending on the hub's state of development. Often the enthusiasm displayed by the trusts has to be constrained by the available resources of the hub.

A hub has the considerable task of usually working with between 60 and 70 trusts. Getting all NHS employees without previous training and experience to understand IP is an arduous task. Web-based training and other methods are being used to publicize the work of the hubs and to encourage employees to think about innovation. The wage packet and trust newsletters are also effective communication tools. Regional competitions, in which employees are encouraged to submit their innovations to their hub for adjudication, have proved an excellent stimulus. The opportunity for publicity is very high, and the excitement generated in a small trust when it wins one of these competitions is remarkable.

Regional competition winners go forward to a national competition, and the publicity and enthusiasm generated by the competition, capped off with health ministers presenting prizes at a national event, bring IP and innovation in the NHS to the fore.

Here are some highlights from 2004/2005:

- the number of hub pipeline opportunities increased from 497 in 2003/2004 to 1250, of which 257 were selected for further development
- 40 licenses were brokered
- many hundreds of entries were made to regional innovation competitions
- three new spinout companies were approved
- income generated approximately doubled from its 2003/2004 level to UK£1.5 million

Of the opportunities selected for further development medical devices accounted for 49%; biotechnology and pharmaceuticals 8%; diagnostics, 8%; IT and training, 28%; and other areas, 7%. Around 30% of the potential innovations had a university link. The following examples show the breadth of these opportunities:

- a handheld device that measures accurately the size of the pupil of a patient's eye at the scene of a road traffic accident
- an electrical device to overcome the effect of "dropped foot syndrome," which is already being manufactured locally for the hub and is the basis of a spinout company
- a simple and low-cost device to eliminate incidents of patients receiving the wrong type of blood
- a device to allow the transfusion to a patient of all blood in a bag
- a company set up by a major hospital to measure glycemic index, important among other things in the management of diabetes, using the expertise of a world-renowned laboratory
- a virtual reality treatment for lazy eye

A comment on time frame is important. When the PSRE Fund was established by the Department of Trade and Industry, the Fund recognized that it would take at least ten years before its success (or failure) could reasonably be measured. The first hub was established in 2001 and the last in 2005. Many of the products arising from the NHS program require extensive testing through trials and other research programs before they can be used on patients, and so success is never easily nor instantly obtained. Even the device to ensure that all blood is completely emptied from a transfusion device would take time to develop and manufacture before it can provide the expected yearly savings of UK£20 million. Research and prototype testing of the dropped foot device began many years ago and it is only now being manufactured.

The growth in income generated in 2004/2005 was satisfying, but much of this income arose from innovations developed some years ago, before the hubs were established. The impact of the hubs and the performance indicators used to measure it are themselves an important piece of ongoing work. The impact reaches far beyond income and numbers of patents.

Each hub has its own Web site and all of them are accessible through the NHS innovations Web site at www.innovations.nhs.uk. The site holds several of the important documents referred to here.

7. APPLICATION OF THE NHS MODEL TO DEVELOPING COUNTRIES

The way that the NHS developed its framework and set up the hubs could be useful for developing countries. Perhaps the most useful aspects are:

- The NHS model will help developing countries if they can agree on a common way to treat IP. IP is difficult to deal with and differences in approaches across countries and organizations increases the degree of difficulty. The United States and United Kingdom models have similar operating principles and are recommended as tried and tested.
- Scientists and other generators of IP in developing countries cannot all be IP experts, nor do they need to be. Generators of IP do

need to recognize that a particular output might be important, and be able to identify individuals who can help promote the innovations. The training for researchers should not focus on how to draw up license agreements but on how to record results, how to avoid disclosure, and how to recognize valuable outputs. The principles contained in the NHS Guide for Researchers (applicable to researchers outside the health fields) seem appropriate.

- Researchers need someone in their organization, to act as a "product champion" who can be their eyes and ears, similar to an R&D manager who often takes on this role in an NHS trust. This advocate does not need to understand the intricacies of drawing up license agreements, but does need to understand the principles contained in the agreements and ensure that the researcher's practices are aligned with those principles. Having a product champion is particularly important when new collaborations are being set up and a collaboration agreement is being established. The handbook produced by the NHS[11] could be adapted for use by developing countries. Product champions could form learning networks as they do in the NHS.
- The IP office needs to be of sufficient scale that it offers the experience and expertise to deal with complex issues. Once a wrong agreement is in place, it cannot be corrected (though it can be amended but this often takes significant negotiation efforts), which is particularly important for developing countries with the variety of new technologies contained, for instance, in agriculture and plants. An IP office similar to that of an NHS hub, dealing with a number of organizations, has much to recommend it. Such an office could attract or have access to the necessary level of expertise, much of it from outside the country, to draw up the agreements that protect the interests of researchers, the developing country, and a collaborator or investor in a technology.

8. CONCLUSION

The NHS hubs are meeting a need and show strong indications of success. Widely valued, they are rapidly becoming the "one-stop shop" for innovation in the U.K.'s national healthcare system. To further support innovation, the Department of Health is setting up a national innovation center that will have a dedicated budget to put on the fast track to the marketplace particularly promising projects. The future looks good provided people are patient! ■

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