

Healthy returns from new NHS IP process



David Chilvers

A new High Throughput IP Process that has evolved within the UK National Health Service (NHS) could improve private sector efficiency. “Efficient” and “dynamic” are not words that immediately come to mind when considering public sector groups, reports Nicki Brimicombe, however, over the last year, a small NHS organisation based in London has set about claiming the terms for its own.

NHS Innovations London (NHSIL) is dedicated to identifying, gaining appropriate IP protection, developing and commercialising inventions made by some of the 170,000 people working for 63 London National Health Service Trusts. Since it was established in December 2005, NHSIL has rapidly grown its portfolio and is currently receiving an average of 10 new invention disclosures per week (approximately 500 per year). In the six months from May 2006 to November 2006, the number of active projects increased from 101 to 147. More significantly, promising projects are progressing towards commercialisation in an orderly, controlled and efficient manner, with a notable absence of congestion. In its first year, 13 products were in product development, 4 in clinical trials, 23 in business development, including nine in licence negotiation. Several health education products have already reached market with ICT software installations also likely to take place in early 2007.

NHSIL operates a novel IP process, called “Xpedite”, which is the brainchild of David Chilvers, the group’s CEO. According to Chilvers, Xpedite is relevant to all highly innovative groups. “Any technology transfer group that receives several hundred or thousands of technological disclosures a year could benefit from Xpedite,” he says. This includes commercial organisations such as those involved in aerospace, telecommunications, engineering and information technology as well as universities and publicly funded groups.

... a team of specialists

Many organisations manage technology transfer by adopting a “cradle-to-grave” approach, whereby one individual manages each project from disclosure, through to commercialisation. This process often proves unsatisfactory, since it is rare to find one individual who has the full skill set needed to deliver informed decisions on all aspects of the process, especially in medicine and healthcare, where the field is so broad. As a result, there is a continuous expansion of the internal project portfolio and workload, resulting in bottlenecks, a decline in focus, efficiency and productivity. According to Mr Chilvers, this stems from a failure to identify and terminate weak projects often and early enough; a lack of prioritisation; poor project management and an absence of information sharing or a clear review process. NHSIL was founded on a completely different approach that centres on a team of functional specialists with relevant scientific/technical specialists who are responsible for a given stage of the Xpedite process.

Xpedite involves five stages and four gates through which each successful project must pass. The process incorporates FastTrack and LeapFrog opportunities for projects with particular promise.

1) Identification (Gate 0)

NHSIL’s Partner Liaison Managers (PLMs) have technical and technology transfer qualifications/know-how. They are responsible for identifying potential projects and raising the profile of the group

to encourage NHS staff to bring their ideas forward. PLMs aim to build relationships with the internal champions (IP Leads, Clinical Leads) at London hospitals. Their work is split on a geographical basis and the profile of NHSIL is maintained through regular face-to-face meetings, interaction at training seminars and contributions to Trust publications. “Most ideas and inventions come from those working directly with patients, since they experience the need for better or improved products and services first-hand,” explains Manish Patel, one of the four PLMs employed at NHSIL.

The PLMs obtain a full disclosure from the inventor and make a preliminary assessment of projects presented by the Trusts to determine if they are relevant and can qualify for IP protection, dissemination and/or commercialisation.

Monday meetings are held at NHSIL to review all projects identified by the PLMs and the initial list is ruthlessly culled before the most promising candidates pass through Gate Zero into “Feasibility”. Of 500 disclosures reviewed in the last year, around 300 have entered feasibility assessment.

A critical factor in increasing the productivity of the organisation has been a determination to identify, even at this stage, the end-point for the project; i.e. the earliest possible stage at which the product can be presented to industry for commercialisation. This allows for a clearer understanding of the milestones, deliverables, timeframes, resources and investment that will be required for the project.

2) Feasibility (Gate 1)

Within this phase, each idea is scrutinised in greater detail to determine if it is appropriate to protect (patent, copyright or trademark). A range of factors are reviewed, including:

- i) fulfilment of unmet need (patient benefit);
- ii) market potential;
- iii) competition;
- iv) Intellectual Property: is it novel and can it be protected? If the product looks very innovative then an early patent search may be initiated, but a full freedom-to-operate is more usually undertaken in the “Validation” phase; and
- v) commercial attractiveness: how attractive will it be for the industry and how much economic benefit is there for the NHS Trust?

Once Feasibility is complete, the outcome is presented at a weekly Monday meeting. In early 2007, Gate 1 turnaround has taken place within 7-14 days for projects where information is readily available. Sometimes, if a prototype or software is already available, the project is FastTracked or Leapfrogged across review Gates directly into Product Development (Gate 3) or Business Development (Gate 4). If the evaluation shows that the project is unlikely to succeed, the inventor and IP lead are notified for discussion prior to the termination of the project. Otherwise, projects are put forward to Validation.

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3) Validation (Gate 2)

During the Validation stage, IP Managers scrutinise each surviving project and undertake detailed research to evaluate its real potential. "Each IP Manager manages only six projects at any one time and projects can remain in this stage from three months to one year," explains IP Manager Sarah Grant, a patent attorney and biochemist. Validation review encompasses the same aspects as the Feasibility group, but in far greater detail. Areas scrutinised include:

- i) market: assessing the value of the product, potential unit sales, market segmentation, what is already available, the strengths of existing products and very importantly the existence of a potential distribution channel;
- ii) IP position: is it possible to achieve a patent, copyright or design right protection and freedom to operate? Is there a conflicting patent or design prohibiting activity in the area that would necessitate a licensing agreement?;
- iii) product: how much development work is required? Some innovations arrive as just ideas or simple sketches and require significant additional work; and
- iv) financials: how much money needs to be invested to take the project further? How much has already been spent and what are the risks associated with further investment? What are the potential returns and when?

In 2005-2006, NHSIL launched its first Proof-of-Concept (PoC) fund, investing in over 20 projects to facilitate progress to commercialisation. For 2007-2009, NHSIL has obtained over £1m (€1.5m) of further PoC funding from the UK Department of Trade and Industry and the London Development Agency.

The Validation team works closely with Business Development and all projects in Validation are reviewed once a month when they are prioritised into "STAR" and priority Level 1 to 4 projects, which dictates the daily work-plan. Only 15% of all disclosures have passed through Gate 2 and it is predicted that this will be reduced to 10% if the current mix of disclosures is maintained. Validation is the most time consuming part of the Xpedite process. Over the last year, the Validation team has evaluated 120 projects and handed 40 on to Virtual Product Development (Gate 3) and Business Development (Gate 4).

4) Development (Gate 3)

The Development team works closely with Business Development to clarify the project end point for NHS Innovations, i.e. what needs to be achieved before a partner can be sought or a start-up company formed. As Torsten Strunz, who focuses on Virtual Product Development explains: "The end point is decided by evaluating the time and cost associated with developing a project and the potential return on investment." For some projects, development work centres on the need to prove unique advantage in order to support a successful patent application. In the case of software projects, this work can take a few months, whereas for devices where trial data is required, it can take over a year.

5) Business Development (Gate 4)

The main objective of Business Development (BD) is to find a company or partner that will license or buy the technology or product. "This is achieved through our own network of contacts and diverse other routes including attending trade shows, internet searches and research at the nearby British Library," explains Alan How, who heads up BD. Most projects are processed in 3-6 months, although some can take longer. If the project is particularly strong and is the basis for a sustainable start-up, then it might warrant the additional work and business planning needed to secure seed funding or venture capital support.

The current expectation is that NHSIL will start-up 1-3 companies each year. Currently there are five under review of which 2 are at the business planning phase. The team expects to generate over 10 commercial (e.g. licensing) agreements in 2007. NHSIL manages the Xpedite process using a commercial IP information management system (IPIMS), which is tailored to the group's activities. All relevant information associated with an opportunity is available to everyone in the team and the database provides a full "audit trail".

. . . constant gardening

Mr Chilvers stresses that the regular review of every project and the ruthless "weeding out" of ideas with little patient or commercial benefit is key to the success of the Xpedite process. He also notes the importance of taking hard and objective decisions early to terminate projects that do not meet healthcare needs and the NHSIL screening criteria. Every project is given a priority level and each Gate has a predefined time limit and milestones to monitor progress and evaluate resource requirements. In addition, each member of a project team has a clearly defined role and workload in terms of number of Gate 1, 2 and 3 projects that they can handle at any time.

Chilvers is keen to highlight how Xpedite helps to control the number of projects held in Validation. "This is where a lot of technology transfer groups get into trouble, as the number of projects under review escalates out of manageable proportion," he reflects. "With Xpedite there is a constant pressure to terminate or progress projects at all stages creating a flow through product pipeline."

As the work and successes of NHSIL have gained greater recognition, the number of projects being identified and submitted for review has increased and in response NHSIL is currently expanding the group. In 2006, Chilvers also recognised that classical market research and business analysis were outdated and did not fulfil the requirements of assessing and selling the value of medical innovations. As a result NHSIL is currently setting-up a Health Economics Unit to research and analyse healthcare and financial data from the Trusts in order to provide more appropriate information for decision-making.

Throughout 2006, several UK and foreign technology transfer organisations visited NHSIL to review Xpedite. Mr Chilvers believes that the Xpedite High Throughput IP Management Process has broad relevance outside healthcare and the public sector, but stresses that it requires a team of at least ten, in order to achieve the breadth of specialism and knowledge to support fully informed decision-making. Fortunately, the benefits of Xpedite may soon become available to smaller organisations as well, since NHSIL is working towards providing consultancy services to third parties.

. . . winners all round

The NHS generates a wealth of creativity and the ideas of NHS staff benefit patients directly and indirectly. Firstly, most ideas emerging from the NHS promote enhanced patient care and improvements in health. Secondly, intellectual property created and owned by the NHS generates wealth that can be ploughed back into healthcare. NHS inventors also gain a share of that revenue.

NHSIL has just celebrated its first birthday, but in its short life it has made a considerable impact on improving the rate at which NHS innovations reach the market. This is good news for patients, inventors and the NHS. For the future, as the Xpedite is adopted more widely by other groups and in other countries, inventors and customers around the world will benefit from its ruthless efficiency too. *