Fact sheet

The Evolution of Biomedical Knowledge: Interactive Innovation in the UK and US

Rationale and objectives

There are an increasing number of breakthroughs in scientific knowledge (e.g. in genomics) that have the potential to radically change medical practice. However, creating new knowledge is not enough to ensure its application in practice. In most cases of biomedical innovation, if breakthroughs are to be fully exploited then novel forms of integrated, multi-disciplinary and networked working arrangements are required. This is what we define as 'interactive innovation'. By studying the dynamics of interactive innovation projects, the project aims to understand the opportunities and challenges of collaborative work arrangements across heterogeneous professional group (e.g. clinicians, scientists, entrepreneurs, policy-makers, managers and lawyers) and organizations (in the public and private sectors).

This project is focused on understanding and improving organization and management of interactive innovation projects. In particular, it is examining the ways in which knowledge is acquired, integrated and applied in interactive innovation projects that are located in different organizational and institutional contexts. Thus the project is designed as a comparative study of interactive innovation projects in the USA and UK. This will generate insights into the impact of the institutional environment (e.g. regulatory, professional, financial, and healthcare systems) on the innovation process. The core methodology couples a broadly-based interview survey with longitudinal case study research, involving the analysis of ten matched cases of interactive innovation in the UK and the US. The ultimate aim is to contribute towards improvements in the exploitation of knowledge in the biomedical field, and thereby reduce the costs and risks associated with failures to initiate and complete interactive innovation projects.

Funding

The research project is funded through UK research grants:
- UK Economic and Social Research Council (ESRC, www.esrc.ac.uk) (80%)
- UK Engineering and Physical Sciences Research Council (EPSRC, www.epsrc.ac.uk) (20%)

Total funding: GBP 525,000.

Duration and timetable

The project duration is three years (Sept. 2003 – Nov. 2006):
- Sept 03 – June 04: Literature review and interview-based survey (50 UK, 50 USA)
- June 04 – June 06: Case studies (4 UK, 4 USA)
- June 06 – Nov 06: Write-up and dissemination

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About 'Evolution of Business Knowledge'

This project is one of 13 projects currently being carried out under a research programme, entitled 'Evolution of Business Knowledge', funded by the Economic and Social Research Council (ESRC) in the UK. Further information: www.ebkresearch.org.

About IKON

IKON is a research unit based at Warwick Business School. IKON stands for 'Innovation, Knowledge and Organisational Networks' and was founded in 1997 to advance understanding of the interactions between innovation, knowledge and networks - primarily from an organisational theory perspective. Its research emphasises a critical understanding of the social aspects of innovation, change, knowledge management and inter-organisational relations. Warwick Business School is among the most highly rated among
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Executive summary

Aims and Objectives

There are an increasing number of breakthroughs in scientific and technological knowledge that could drastically improve the efficiency and effectiveness of medical practice in the delivery of both treatments and services. These breakthroughs (e.g. in genomics research) have the potential to be exploited by private (pharmaceutical, biotechnology firms) and public (health service providers, social services) sector organisations as viable medical solutions.

Achieving such breakthroughs, however, is not sufficient for fuelling actual biomedical innovation since many such breakthroughs fail to be translated into changes in medical practice, despite major development investments. Failures often occur because breakthroughs cut across existing disciplinary and professional boundaries and require major changes in practices and relationships across medical professionals, scientists and managers.

In the biomedical field (life sciences applied to medical practice) it is, therefore, not simply the possession of new knowledge that will create success in terms of improved medical practice but, rather, the ability to *integrate* knowledge across an increasingly distributed array of professional groups and organisations.

This requires the establishment of novel, collaborative working arrangements across heterogeneous groups of clinicians, academic scientists, industrial scientists, social scientists, managers and practitioners across public and private sector organisations. These groups will need to routinely work together in acquiring, integrating and applying knowledge if the innovative potential of scientific breakthroughs is to be fully exploited. We refer to this process as 'interactive innovation'- innovation encompassing the integration of knowledge across different scientific, professional and organisational groups.

The aim of this research project, then, is to improve the development and exploitation of biomedical knowledge by understanding how knowledge may be acquired, integrated, and applied in interactive innovation projects aimed at the improvement of medical treatments and service delivery. In so doing, the research aims to help to reduce the costs and risks associated with failures to exploit breakthroughs in scientific knowledge and research into development and practice.

To achieve this requires studying and understanding social interactions and networking relationships across occupational and professional communities in interactive innovation projects. Moreover, given the leading position of the USA in biomedical innovation, and the potential for lessons to be learnt, the research compares and contrasts interactive innovation in both the UK and US. Specifically, through the development of collaborative working arrangements in our own research, we aim to understand the processes underlying the evolution of knowledge in a field where science breakthroughs have the potential to lead to radical innovation in diagnostic and therapeutic medical treatments and services.

Within this broad aim, the research has a number of more specific objectives:

- To compare and contrast the UK and US, identifying the contextual influences that can facilitate (or impede) the evolution of knowledge which can support innovation in medical treatment and service delivery.
- To compare different collaborative interactive forums for medical innovation, identifying factors that facilitate and impede the management of knowledge in these forums
- To develop practical recommendations and guidelines for (a) policy makers and, (b) those attempting to manage interactive forums for the evolution of biomedical knowledge.

Research Method

There are two phases to the research design:

Interview-based survey. Primary data collection in Phase 1 was an expansive interview-based survey in the US and UK with about 102 individuals (52 in the UK and 50 in the USA) who have worked on both successful and unsuccessful innovation projects. Interviewees were chosen to represent multiple stakeholder groups (clinicians, scientists, academics, industrialists, investment agencies) and organizations (biotechnology, pharmaceutical, healthcare, public research

organizations, technology transfer, public policy). Interviewees had experience of managing or participating in interactive innovation projects for the development of medical treatments and service delivery in scientific fields using breakthroughs in genomics. The purposes of this survey were to: identify focal communities in interactive innovation initiatives; understand their 'modus operandi' in the context of their own organisations, cultures and wider contextual arrangements; identify the range of factors in the UK and US – structural, social, political and cognitive – that enabled or constrained the interactive innovation initiatives in which individuals were involved.

Case Studies. This phase involves ten longitudinal case studies of interactive innovation projects which are aimed at producing commercially viable biomedical treatments and/or services. The emphasis is on projects in early stage development (e.g. preclinical to Phase 1 and 2 clinical) as Phase 1 interviews revealed this to be a crucial point in the interactive innovation lifecycle. The approach is to projects over time in an attempt to explain how patterns of events located in particular contexts lead to particular outcomes. The objective of Phase 2 is to gain an understanding of those factors that facilitate or impede the management of knowledge in interactive innovation projects in real time.

To compare interactive innovation in the UK and the US, cases are being matched across scientific fields identified as having a high requirement for interactive innovation. These include: (i) development of new diagnostics and treatments based on breakthroughs in genomics; (ii) development of pharmaceutical drugs in the treatment of genetic disorders; (iii) development of new services for the delivery of treatments based on genomics. Cases have been selected to represent different modes of organizing interactive innovation, as identified in Phase 1 (see preliminary findings).

The interview protocol has been designed from the data collected in Phase. Repeat interviews are being conducted where feasible to check progress against expectations. Where possible, site visits are being arranged to allow participant observation (e.g. around meetings). Access is also being sought to project documentation and electronic communication (e.g. web-based discussion forums). During interviews, respondents are asked to describe their own role and expectations of the innovation process as well as those of their network partners, and to discuss the processes and mechanisms whereby knowledge is acquired, integrated and applied.

Expected Outputs

Beneficiaries from the research include pharmaceutical and biotechnology firms, medical and healthcare professionals, scientists, venture capitalists and policy-making bodies. Case partners will be able to use the research outputs to improve the likelihood of success of their interactive innovation initiatives.

Aside from theory building, the research will develop *practical recommendations and guidelines* for improving the exploitation of knowledge through interactive innovation. These will be in the form of *targeted reports and presentations* for: those attempting to manage interactive forums for the development of biomedical knowledge into commercially viable medical treatments and services (specifically our case collaborators); publicly accountable bodies (government, healthcare, professional groups) who fund, support and set policy for interactive innovation initiatives; pharmaceutical and biotechnology firms seeking to reduce the costs of failure associated with development.

Preliminary findings

1. Models of Interactive Innovation

All (or nearly all) biomedical innovation projects can be characterized as 'interactive' at least in the sense that they are highly interdisciplinary and involve the integration of knowledge across scientific, professional and organizational groups. Many projects can also be characterized as 'systemic production networks'- formal inter-organizational units jointly producing a product or service in pursuit of a super-ordinate goal (Alter and Hage, 1993). Therefore, the concept of interactive (or distributed) innovation (cf. Massey et al, 1992; Rothwell, 1994; Coombes et al, 2002) is not sufficiently differentiated to capture variation in the management and organization of biomedical innovation. Drawing from Phase 1 findings, we propose 2 critical dimensions of interactive innovation (see Figure 1 attached). We have labeled these, for simplicity, 'Organizational Integration' and 'Knowledge Integration'.

Figure 1. Conceptual framework: Models of Interactive Innovation

		Organisational integration	
		Loosely coupled/ decentred	Tightly coupled/ centred
Knowledge Integration	Low	US: NewPharma UK: SampaTech	US: AmericanBio (FGT project) UK: Lynx
	High	US: Circulasis UK: Theramed	US: AmericanBio (ELBOW project) UK: Newmore Global

Organizational integration focuses on the governance, organization and management of the innovation process. Variations along this dimension range from networked /loosely-coupled modes to organizationally integrated/tightly coupled modes. In the former, innovation is pursued within a loosely coupled network of organizations, anchored around a lead (often public research or small biotechnology) organization, but with a significant amount of the work being conducted in other organizations. Management is decentralized and dependency on central resources is low. Where formal contracts exist, these focus on mutual obligations and the allocation of future gains (e.g. revenues generated through patents). Knowledge flows via 'open channels' – characterised by diffuse linkages & 'knowledge spillovers' (Owen-Smith & Powell, 2004). In contrast, in organizationally integrated modes, most innovation activity is carried out within a focal firm (typically a large biotech or pharma company) but with clearly identified parts of the work (e.g. manufacturing, clinical trials) being formally contracted to outsiders. Management is relatively hierarchical (often matrix management) and there is high dependency on centralized resources. Knowledge flows via closed 'conduits', or pipelines (Owen-Smith and Powell, 2004), characterized by legally binding contracts to secure deliverables and protection of IP. These dimensions form the basis of our case selection in Phase 2 (as indicated in Figure 1).

Knowledge Integration is linked to the requirements for distributed knowledge to be integrated. Whilst all projects require the integration of knowledge across disciplines and/or organizations, they differ in terms of the intensity of knowledge sharing between those involved in upstream science (e.g. scientific research) and those involved in downstream application (e.g. clinical practice). In low knowledge integration projects (e.g. the development of a new vaccine, or new weight loss drug), medical need is well-established and implications for medical practice are (or are seen to be) relatively easy to forecast. In such cases the requirement to involve end users in product development is lower. In contrast, in high knowledge integration projects (e.g.

in tissue engineering), medical need is uncertain and/or contested and the implications for medical practice are difficult to forecast. Therefore significant efforts are made to enlist clinical practitioners and integrate their expertise into the early design and development of the product or service. One implications of this model is that constraints and enablers to knowledge management would be expected to be contingent on the types of interactive innovation activity.

2. Institutional Influences on Interactive Innovation

Table 1 (below) summarizes the factors reported in Phase 1 interviews as critical in influencing interactive innovation projects in the biomedical field, together with literature supporting the importance of these.

Our findings also suggest similarities and differences across the UK and US. Broadly similar issues were: (i) the organization of corporate R&D - large pharmaceuticals operate on a global basis, so generating similar constraints across the UK and US (e.g. constraints on radical innovation in pharmacogenetics due to emphasis on investment in 'blockbuster' drugs); (ii) access to high risk finance for early stage development (similarly difficult in the UK and US, in particular for innovation in diagnostics); (iii) the operation and effects of intellectual property laws; (iv) policy around the approval and regulation of new drugs and devices (e.g. which reinforces a linear R&D model and can limit knowledge integration along the development pipeline).

Differences included: (i) Labour market mobility. Here interviewees reported greater availability of scientific 'entrepreneurs' in the US than the UK (e.g. clinicians with dual careers in clinical practice and industry, or research scientists with commercial training) and hybrid professional identities and careers were seen as more legitimate in the US (e.g. medical doctors simultaneously working in hospitals and biotechnology firms). In contrast, in the UK, professional identities/values were more narrowly tied to *either* science, *or* medical *or* commercial roles. We also found some evidence that in the US venture capitalists might have stronger networks with lead scientists and scientific training (e.g. through PhD training). These findings suggest that the US context is more supportive of *integrative capabilities* (i.e. the movement back and forth between basic science and industry – cf. Owen-Smith et al, 2002) which support knowledge integration; (ii) Access to science and technology – there are more *varied* (if not more) mechanisms for commercialising academic knowledge in the US, whereas UK universities focus this activity on Technology Transfer Offices, many of which are perceived negatively by research scientists (as a 'blocking step'). UK universities tend to be more strongly driven by revenue generation through technology transfer. However, this can have perverse effects, limiting incentives for individual scientists to commercialise their work.

Summarising, early findings indicate that the US institutional context supports the co-joining of knowledge and practices across scientific, medical and commercial domains and this plays a critical role in the translation of knowledge. In contrast, the UK context supports the distribution of knowledge/practice across scientific, medical and commercial domains. UK policy is typically aimed at knowledge transfer – i.e. connecting or ***'bridging'*** science and industry. However, without addressing the problems of distributed knowledge/ practice, this is unlikely to have significant impact. For example, our evidence suggests that 'translational' funding is often merely appropriated to support established scientific research. Alternatives would be to develop policy centred on ***'bonding'*** (e.g. creating shared incentives and opportunities for shared practice and career mobility) rather than 'bridging'.

Table 1. Institutional Factors Influencing Interactive Innovation.

	Elements	Indicative References
Access to Science & Technology	• Technology transfer • University-industry networks	Owen-Smith, Riccaboni, Pammolli, & Powell, 2002; Casper et al., 2001; McMillan & Hamilton, 2003; Lehrer & Asakawa, 2004
Labour Market	• Career pathways and incentives, • Personal mobility, • Professional identities	Zucker & Darby, 1997; Audretsch & Stephan, 1996; Dasgupta & David, 1994
Capital and Finance	• Venture Capital, • In-house R&D funding • Public and third-sector funding	Lockett, Murray and Wright 2002; Tylecote 1999; Manigart et al 2000; Powell, Koput, Bowie, & Smith-Doerr, 2002
Health Care System, Government Policy & Regulation	• Governance of health care • Regulation of drugs and medical devices • Industry-specific government support	Gelijns & Rosenberg, 1994; Moran & Alexander, 1997