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<td>TITLE</td>
<td>The Evolution of Biomedical Knowledge: Interactive Innovation in the UK and US</td>
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**EXECUTIVE SUMMARY**

Biomedical innovation is defined as the process of creating and applying scientific and technological knowledge to improve the delivery of human healthcare and the treatment of disease. Typically this process is ‘interactive’, with knowledge evolving through collaborative, networked relationships across R&D scientists/managers in biotechnology and pharmaceutical firms, academic scientists, clinicians, clinical research organizations, manufacturing firms and regulators. Breakthroughs in scientific knowledge (e.g. in genetics) potentially generate radical innovation in therapeutic treatments and services. However, attempts to commercialize and apply these to medical practice are often thwarted by institutional-level problems (e.g. obtaining regulatory approvals and investment finance) and by the many barriers to knowledge integration amongst the various groups and organizations involved, generating a ‘translational gap’.

This research - conducted by members of the Innovation, Knowledge and Organizational Networks (IKON) Research Centre - aimed to understand the key processes underlying the evolution of knowledge required for biomedical innovation. Specific objectives were to:

1. Compare and contrast the UK and US, identifying institutional influences that can facilitate (or impede) the evolution of knowledge to support innovation in medical treatment and service delivery

2. Compare different collaborative interactive forums for biomedical innovation, identifying factors that facilitate/impede the management of knowledge

3. Develop a multi-level conceptual framework that encapsulates these findings and a more refined taxonomy that captures variation in interactive biomedical innovation

4. Develop practical recommendations and guidelines for (a) policy makers and, (b) those managing interactive forums for the evolution of biomedical knowledge.

The research focused on early development projects (moving from proof-of-concept to clinical trials) aimed at radical innovation (which potentially change medical practice) such as the development of new biologic drugs and tissue engineering treatments. Using an interview-based survey of lead experts in the UK and US, followed by in-depth, longitudinal case studies of innovation projects, it identified critical processes, at the macro (national), meso (inter-organizational) and micro (project) levels, facilitating and/or impeding interactive innovation in the biomedical sector in the UK and US.

At the macro level key factors related closely to Owen-Smith et al’s (2002) ‘integrative capabilities’ (the linking of basic science and commercial/clinical activity through the movement of scientists to/from industry) and ‘relational capabilities’ (the ability to form and sustain collaborative inter-organisational relationships). Our findings confirmed that the US is more supportive of biomedical innovation, especially with regard to integrative capabilities. Institutional mechanisms explaining differences between the UK and US included: (i) access to human resources (greater demarcation between academic and clinical/commercial career paths and value systems was observed in the UK); (ii) access to finance (greater translational funding gaps between basic research and commercialization were found in the UK and US investors had much closer links with
science and lead scientists); (iii) access to technology (marked differences in expertise and approaches to technology transfer and intellectual property were observed); and (iv) healthcare systems (greater tensions between commercial and clinical/scientific aims were apparent in the UK due to public healthcare provision).

At the meso level, key factors related to the modes of organization used to support biomedical innovation: whether they were relatively centralized (‘tightly coupled’) or decentralized (‘loosely coupled’); and whether high or low ‘knowledge boundaries’ existed across professional and disciplinary groups. Loosely coupled projects with high knowledge boundaries were particularly problematic in the UK as they relied more heavily on integrative and relational capabilities.

Such differences mean that UK technology transfer cannot simply mimic US initiatives. Greater emphasis needs to be placed on bonding scientific, commercial and clinical groups and practices in the UK, rather than continuing to try and bridge these gaps through, for example, network funding. Bonding, however, takes significantly more time and investment than currently provided for in most R&D policy initiatives. For example, the Genetics Knowledge Parks initiative (examined in our research) provides an illustration of the unintended effects of such policy in disrupting existing scientific collaborations and encouraging ‘knowledge protectionism’ through competition for funding.

At project level, we identified crucial mechanisms that help organisations develop and exploit integrative and relational capabilities. These include: aligning interests and expectations across industry partners via, for example, ‘two way’ due diligence; establishing commercial as well as scientific credibility with investors; deploying existing networks and ‘opinion leaders’ to engage clinical users and (as applicable) regulators early on; using ‘product magnets’ and ‘symbolic figureheads’ to motivate interest, span boundaries and engage stakeholder groups (including clinicians and patients). A major contribution of the research was to develop a new theoretical framework that relates these project-level mechanisms systematically to macro capabilities, highlighting their role in mediating the effects of such capabilities on biomedical innovation processes and so creating constraints and opportunities for those involved (see Swan et al, 2007). For example, our research suggests that particularly novel and radical innovation projects in the UK, not supported by a large centralised resource base, should find these mechanisms helpful in enabling commercialisation and overcoming some of the barriers to innovation arising from the relatively unfavourable institutional context.

To develop our multi-level analysis further, we have applied a sectoral systems of innovation approach (cf. Malerba, 2004), which emphasises knowledge and learning, actors and networks, and institutions as ‘building blocks’ that support innovation. Our research has developed this framework, using it to analyse interactions amongst these ‘building blocks’ and emphasising individual and firm agency. Thus the research not only highlights the importance of cumulative knowledge, networking and power in creating conditions for successful innovation, but also their constraining effects on future innovation arising from technological and network ‘lock ins’.

The research also highlights the limitations of project management techniques for managing interactive innovation. Early development typically entails a portfolio of subprojects, working to different timings and deadlines. These are often coordinated across several organizations, with outcomes that are unknown or unknowable, thereby
increasing complexity, risk and coordination problems. The research suggests that traditional project management techniques (typically focusing on single projects with plans/goals known ahead) may be unhelpful. Closer attention therefore needs to be paid instead to ‘portfolio’ project management and boundary work (e.g. coordinating communication flows, incentives, interests and outputs across subprojects).
FULL RESEARCH REPORT

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

1. Theoretical Background

Innovation in the pharmaceutical and biotechnology sectors is a major source of UK economic advantage (PICTF, 2005; ABPI 2006; Datamonitor, 2006). However, despite an increasing number of breakthroughs (e.g. in genetics) that have the potential to radically change healthcare, the challenges of translating new knowledge into improved clinical practices are shown by the increasing time and costs involved in drug development (CMR International, 2004). Even where clinical effectiveness is established, translational challenges persist, often due to the ‘disruptive’ effects of innovations in causing shifts in practices and relationships amongst the various stakeholders involved (Christensen, 2000; Dopson, 2005). Thus, it is not just the availability of knowledge that generates innovation in the biomedical domain, but the ability to integrate knowledge across a distributed array of professional groups and organizations, including end ‘users’ (Powell et al, 1996, Owen-Smith et al, 2002; Ferlie et al, 2005).

Biomedical innovation is defined as the process of creating and applying scientific and technological knowledge to improve the delivery of human healthcare and the treatment of disease¹ (Rasmussen, 2005). Typically this process is ‘interactive’, with knowledge evolving through collaborative, networked relationships across R&D scientists/managers in biotechnology and pharmaceutical firms, academic scientists, clinicians, clinical research organizations, manufacturing firms and regulators (Rothwell, 1994; Massey et al, 1992, Powell et al, 2005). Understanding such interactive innovation processes - where knowledge is produced through (rather than before) use - demands new models that take seriously such issues as the organization of networks, boundary spanning activities, the mediating role of trust and legitimacy, professional power and influence, and combinations of different forms of expertise (Swan and Scarbrough, 2005). It also demands attention to the institutional context in which innovation unfolds (Owen-Smith et al, 2002), bringing into question the adequacy of the existing structure or ‘anatomy’ of the biopharmaceutical sector in supporting innovation and commercialization (Pisano, 2006). This research aimed, then, to understand the processes underlying the evolution of knowledge required for biomedical innovation in the institutional contexts provided by the UK and US.

Our epistemological basis was to treat knowledge as dialectical – situated in social and organizational practices and relationships that are themselves embedded in wider institutional contexts (Tsoukas and Vladimirou, 2001; Lam, 1997). This points to a critical focus on networks of relationships and work practices through which knowledge is constructed (Brown and Duguid, 2001) and on the distribution of knowledge and power across organizational, occupational and professional groupings (Brown & Duguid,

¹ This includes new drugs, diagnostics, and drug delivery regimes for human use, but excludes animal, agricultural and natural resource biotechnology applications
2001; Lam, 1997; Giddens, 1990; Hage and Hollingsworth, 2000), together with
associated requirements for integration. Theoretical lenses of social constructivism (e.g.
Tsoukas and Vladimirou, 2001), and related frameworks deriving from practice-based
theorising (e.g. Brown and Duguid, 2001) and epistemic cultures (e.g. Knorr-Cetina,
1999), were thus applied as appropriate. These literatures are linked by their premise that
knowledge claims co-exist with political interests and institutionally embedded network
relationships and structures. Moreover, power was treated, not as a property of a
particular individual/group, but as embedded in networks of interaction (Callon, 1986).
Thus, what counts as valid biomedical knowledge is contested, as more or less powerful,
medical professionals and scientists with particular vested interests seek to sustain power
and control within their own knowledge domains and over their own work practices
(Abbott, 1988; Drazin, 1990). Explicitly incorporating power into our empirical analysis,
allowed us to gain insights into the processes by which social communities involved
resist and/or change their practice and innovate (Fox, 2001; Swan and Scarbrough, 2005).

By adopting this theoretical stance we were able to develop a multi-level analysis of the
political, social and professional structures and networking processes surrounding the
production and evolution of biomedical knowledge (Gittell and Weiss, 2004). The
research focused on early stage development projects aimed at ‘radical’ innovation (such
as new biologic drugs and tissue engineering treatments) to identify critical processes
innovation at macro, meso and micro (project) levels driving interactive biomedical
innovation. The decision to conduct comparative analysis of the UK and US was based
on the important similarities and differences between these two particular national
contexts - both being liberal market economies with national systems of innovation that
are largely supportive of biotechnology innovation and, yet, with important differences in
institutional-level conditions which govern biomedical innovation (Casper and Kettler,
2001; Swan et al, 2007).

2. Objectives

The overall aim of the research, as originally specified, was to understand the processes
underlying the evolution of knowledge in the biomedical field, where breakthroughs in
science have the potential to lead to radical innovation and improvement in medical
treatments and services. The objectives were:

1. To compare and contrast the UK and US, identifying the institutional factors that
facilitate (or impede) the evolution of knowledge which can support innovation in
medical treatment and service delivery

2. To compare different collaborative interactive forums for biomedical innovation,
identifying factors that facilitate and impede the management of knowledge in these
forums

3. To develop a multi-level conceptual framework that encapsulates these major
findings and a more refined taxonomy that captures variation in interactive
innovation in the biomedical domain

4. To develop practical recommendations and guidelines for (a) policy makers and, (b)
those attempting to manage interactive forums for biomedical innovation
In response to the panel’s feedback at the outline stage, 12 ‘hypotheses’ were developed as guiding propositions for analysing objectives 1-3. These are included in Appendix 2, cross-referenced with our papers that provide analysis pertaining to each. The majority (10 from 12) of the hypotheses received qualified support, bearing in mind that this research employed a qualitative, constructivist methodology.

The objectives remained unchanged and each has been successfully met – as indicated in the remainder of the report, below.

3. Methods

The research was a multi-level, multidisciplinary comparative study. It was ambitious in scope and scale – international multi-level analysis has not been attempted in any previous research on biomedical innovation. The research focused on:

- Macro level institutional influences on biomedical innovation and key differences between the UK and US
- Meso-level relationships among project stakeholders, including networks within and between organisations and the ‘boundary spanning’ activities involved
- Micro-level organization and management of biomedical innovation in specific project settings and the role of individual actors in the innovation process.

Clearly, in a 3-year project it is impossible to trace an entire biomedical innovation process. We therefore selected radical innovation projects that have the potential to change existing clinical practices (e.g. tissue engineering) and those in early development (at the point of moving from proof of concept into clinical trials). This was because: (i) radical innovation is high risk but potentially yields the highest returns and improvements in health; and (ii) early development is the point at which many biomedical innovation projects fail. These kinds of project pose major challenges since they rely on collaboration across diverse organizations, professional groups and scientific disciplines.

The methodology comprised two linked phases:

**Phase 1** involved a systematic literature review - following the methodology deployed by Pittaway et al (2004) - and an interview survey of 97 stakeholders (44 in the UK, 53 in the US) with experience of interactive innovation in the biomedical sector. This phase allowed us to identify key enablers and constraints on biomedical innovation in the UK and US (Objective 1) and to develop a framework and initial taxonomy for understanding critical variation in the organization of interactive innovation projects (Objective 3).

Initially, interviewees were identified in discussion with our UK and US Scientific Advisory Boards (SAB) established to oversee and (in line with our theoretical stance on interactive innovation) actively inform the research design. SAB members comprised lead clinicians and scientists and representatives from industry and policy groups (see Appendix 3), selected due to their prominence in the field. Additional interviewees were identified using a ‘snowball sampling’ technique, which is appropriate when research is exploratory and population parameters are unknown (Saunders et al, 2000).
Phase 2 comprised 10 longitudinal case studies (6 US; 4 UK) tracing innovation projects through multiple visits over a 2-year period (original target N=8). The unit of analysis was the innovation process, with cases being selected on the basis of: the project being both innovative and interactive; the phase of work (early development); the location of the case within the taxonomy developed Phase 1 (see below); the scientific area; and the timing of the innovation project to allow the capture of both historic and ‘real time’ data.

141 interviews were conducted with project participants (from different organizations involved) across cases. These data were triangulated with observation of team meetings and analysis of company reports and project documentation. This phase allowed us to identify management and organizational processes at the meso (inter-organizational) and micro (project) levels that played a crucial role in influencing collaborative, interdisciplinary working and knowledge integration in specific kinds of innovation project (Objective 2). It also allowed us to further refine the framework developed in Phase 1 (Objective 3).

Data from both phases were coded (NVivo) and Phase 1 data was analysed using the ‘memoing’ technique (Miles and Huberman, 1994). Due to the complexity of the Phase 2 cases, each was investigated by two researchers. On completion of fieldwork, detailed case descriptions were produced (average 10,000 words) containing primary data (quotes from interviews, inserts from documents, etc) and structured thematically. All case descriptions were content analyzed by the entire team in order to establish inter-rater agreement on key points of interpretation. The data were further validated through presentations and discussions at SAB meetings and through feedback to case companies and the distribution of a General Report.

4. Results

The presentation of results is structured according to macro, meso and micro levels of analysis. Numbers in [brackets] refer to our related publications and other outputs listed in Appendix 4.

4.1 Macro-Level: Institutional Influences and National Differences

Understanding key institutional factors influencing biomedical innovation across the UK and US (Objective 1) was a primary aim of Phase 1. This led to the identification of a number of factors that dovetail with what Owen-Smith et al (2002) describe as ‘integrative’ and ‘relational’ capabilities [1] [2] [7]. Integrative capabilities refer to the translation of basic research into commercial applications through the movement of scientists to/from industry. Relational capabilities refer to the inter-organisational links established to facilitate innovation. Our research reinforced other work (e.g. Casper and Kettler, 2001) that suggests that the UK context is less supportive of the development of these capabilities than the US [2] [16]. In addition to identifying important differences in the regulatory environment [2], it highlighted four key institutional mechanisms that explain these differences:

Access to human resources: Career and incentive systems proved more of a barrier to biomedical innovation in the UK than in the US. Career paths are more fluid in the US, allowing scientists and clinicians to move back and forth between public and commercial activity without detriment to their careers or status [1]. Combining basic science and
commercialization is a more established goal in the US, generating an advantage in being able to exploit scientific knowledge for clinical development. In contrast, relationships between public research organizations (PROs) and private firms in the UK are more distant and there are greater boundaries between basic research, commercial and clinical professions [2].

**Access to technology:** This refers to high quality basic science as well as to appropriate regulatory policies and institutions for technology transfer to commercially exploit the science base. The UK has to some extent emulated the ‘Bayh-Doyle Act’ in the US for intellectual property (IP). However, our findings suggest that it still lags behind the US in its overall approach to technology transfer [2]. One reason is the lack of clarity of ownership of IP in early development, particularly in collaborations involving joint university-industry funding. Whilst UK universities produce roughly equivalent numbers of patents and licensing agreements per-unit research fund, these generate significantly lower income. UK, technology transfer offices usually demand a larger equity share and universities tend to view IP as a way of making money, which lowers incentives for entrepreneurship. In contrast, lead US universities (such as Massachusetts Institute of Technology - MIT) take a more ‘hands-off’ approach and view entrepreneurial activity as ‘reputation enhancing’ rather than income generating [2] [7] [16].

**Access to high risk finance:** Access to high risk finance for early development is influenced by national financial institutions (especially venture capital) and general market confidence. Significantly, there are differences between the major sources of finance in the UK and US biotechnology sectors, in terms of size, composition and characteristics of investment decisions [16]. In both the US and UK, however, there is a major gap in early stage financing to support projects reaching proof of concept and just entering clinical development (e.g. between 2003 and 2004, this decreased in the UK by 30%). Large pharmaceutical firms were found to be increasingly looking to partner with projects that had already entered clinical trials in order to reduce risk, so placing additional financial burden on smaller biotechnology firms.

**Health care systems:** The NHS is regarded as a major global source of innovation in health and provides the world’s largest accessible population of patients for clinical trials. Yet, conflicts between public and private sector values, incentives, interests and funding limit innovation in the NHS. In addition, unlike the US, clinical research in UK hospitals was widely seen as being in decline or as increasingly dis-incentivised, leading to a significant gap in translating innovations into practice.

**4.2 Meso Level: Modes of Organizing Interactive Innovation**

Phase 1 of the research generated a taxonomy mapping typical variation in modes of organizing biomedical innovation projects at the meso level. This was used to select cases and was refined further in Phase 2 (Objective 3). It consists of two broad dimensions, along which biomedical innovation projects can be characterized [1]:

**Organizational coupling** refers to the governance, organization and management of the innovation process and the pattern of collaboration amongst partners. Variation here ranges from networked/loosely-coupled relationships, on the one hand, to more hierarchical/tightly-coupled organization on the other.
Knowledge boundaries relates to knowledge flows across the different knowledge domains involved and can be considered as ranging from high to low. Most innovation projects were multidisciplinary. The important issue, then, was whether or not projects required new ways of working across these disciplines and/or disrupted existing knowledge/practice boundaries (cf. Carlile, 2004), in which case they were classified as having high knowledge boundaries. These arose in situations where there was greater novelty, where medical need was uncertain or contested, and where implications for medical practice were difficult to forecast.

Combining these two dimensions provides a new framework (Figure 1) for classifying different modes of organizing interactive innovation projects.

**Quadrant I** was typically populated by small early stage spin-off companies founded by academic entrepreneurs. There was high dependency on the parent university and multiple sources of funding were sought for facilities and specialist expertise. The development process required relatively low levels of knowledge integration and low knowledge boundaries. Innovations here might result in significant improvements in treatment, but were less disruptive to existing modes of treatment delivery.

Projects in **Quadrants II and III** were typically led by larger companies. Quadrant II was less central to our study as projects here were usually aimed at incremental improvement of existing therapeutics, with technology being either developed in-house, acquired or licensed. Quadrant III, on the other hand, describes cases where the companies ventured into highly innovative areas, where the development of breakthrough technologies placed demands on the organization to collaborate with basic researchers and where constant interaction with end users (health professionals) and regulators was required. Inter-organizational relationships in Quadrants II and III were tightly controlled by the focal organization and usually based on formal contractual agreements.

**Quadrant IV** also contained highly novel projects but resources and management were decentralised. The novelty of the technology, or combination of technologies, generated

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2 Only Phase 2 cases are included here and pseudonyms are used
an informal inter-organizational ‘web’ of smaller companies and collaborating PROs. These ‘sexy technologies’ created an aura of attraction that drove interest and collaboration. These projects depended on highly networked individuals to orchestrate loosely-coupled, decentralized projects.

Our multilevel analysis enabled us to explore the link between national level integrative and relational capabilities and modes of organising biomedical innovation at the meso level (Objective 3). Although micro-level mechanisms were also important in moderating the impact of macro level capabilities (see section 4.3 below), our analysis indicated that the influence of integrative and relational capabilities varied in their importance across quadrants – with the former being more crucial in the case of start-ups, for example (Quadrant I) and the latter more important in the case of strategic alliances centred on focal biotech companies (Quadrant III). Most significantly, Quadrant IV projects relied heavily on both integrative and relational capabilities. Success in this quadrant was therefore, relatively more difficult to achieve in the UK, which, as already noted, is generally less supportive of these capabilities [1] [2] [7] [16]. Figure 2 summarises the relationships between these two sets of dimensions.

Genetics Knowledge Parks (GKPs) constitute a major policy initiative in the UK geared towards the development, integration and application of genetics knowledge. As such, they were a particular focus, with one GKP (‘Yestergen’) providing a case study project. In addition, interviews were conducted across all GKPs as an extension to the work specified in the original proposal (see section 8 below). This additional work highlighted the importance of understanding the politics of organizing for biomedical innovation and the unintended effects of such a policy – for example, in the disruption it caused to existing collaborations and the encouragement of ‘knowledge protectionism’ via competition for funding [3] [27].
4.3 Micro level: Processes for Developing Biomedical Innovation

Cross-project analyses identified eight processes, or mechanisms, at the project level that were crucial in influencing collaboration across the partners involved (**Objective 2**). These are summarised in Table 1.

**Table 1: Critical Mechanisms Influencing Biomedical Innovation Projects**

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<th>Mechanisms Linked to Integrative Capabilities</th>
<th>Illustrative Case Examples</th>
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<tr>
<td>1. Access to people working at interstices of networks to acquire knowledge &amp; reproduce skills base</td>
<td>Reliance on ‘deal breakers’ to help commercialize potential products (NewPharma)</td>
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<tr>
<td>2. Establishing scientific and commercial credibility in project team in order to ensure funding through partnering, VC or research funds</td>
<td>Importance of scientific founders, host university and CEO with prior start-up experience in providing credibility (NewTissueCo; Diagnostic Labs)</td>
</tr>
<tr>
<td>3. Symbolic figureheads</td>
<td>Leading scientist's personal vision and commitment to commercialization (NewTissueCo)</td>
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<tr>
<td>4. Career perceptions and professional values in relation to motivation to engage with innovation commercialization activity</td>
<td>Scientists and clinicians placing scientific/altruistic reasoning in opposition to commercial objectives, thus constraining commercial activity (SampaTech)</td>
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<th>Mechanisms Linked to Relational Capabilities</th>
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<tr>
<td>1. Alignment of interests and expectations across partner organizations</td>
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<tr>
<td>2. Building upon existing networks to generate resources and sustain more risky and long term projects</td>
</tr>
<tr>
<td>3. Using networks to shape regulations and ensure approval</td>
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<tr>
<td>4. Product ‘magnets’</td>
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A major contribution of this research has been to relate these mechanisms systematically to macro integrative and relational capabilities, highlighting the ways in which they mediate the effects of such capabilities on the processes and outcomes of biomedical innovation – see Table 1 [1]. So, for example, while it may be important that projects in Quadrant IV benefit from a context in which integrative and relational capabilities are high, local conditions may compensate and enable projects to be pursued successfully through the mechanisms identified above. Thus, a major finding is that the influence of institutionalised capabilities on innovation processes at the micro level is systematically related to different modes of organising innovation, in the ways shown in Figure 2 [1]. Consequently, generic statements about relative national advantage in biomedical innovation need to be tempered by a consideration of the kinds of project and combination of mechanisms deployed at project, firm or sector level (cf. Casper and van Waarden, 2005).

Further understanding of the nature of relationships across levels of analysis has been helped by applying a sectoral systems of innovation approach (Malerba, 2004). Our research has extended this approach by emphasising the agency of individuals and firms as actors in biomedical innovation processes [15]. It has also highlighted the importance of cumulative knowledge and networking in creating, not only conditions for successful innovation, but also important constraining effects on future innovation through the technological and network ‘lock ins’ that are created [15]. We refer to this as an ‘appropriability paradox’ and present it as an explanation for the inappropriateness of the existing ‘anatomy’ of the biopharmaceutical industry for encouraging commercialisation (Pisano, 2006).

Further work is beginning to focus in on relating the indeterminacy of exploratory projects in the biomedical field to the importance of power dynamics and identity construction [19] [3] [5]. These processes not only serve to shape the development of projects and organisations, but also the institutional conditions within which they are embedded – thereby addressing the effects of micro level processes on reproducing and/or changing macro level conditions within the sector (cf. Giddens, 1990).

The research has also yielded important insights into processes of project organisation and management at the micro level. Early development biomedical innovation projects typically entail a portfolio of subprojects (e.g. for clinical trials, manufacturing, business planning) where outcomes are unknown and, to a large extent, unknowable in advance. In this context, traditional project management techniques (focusing on single projects with plans and goals relatively well known in advance) are not helpful. Rather, closer attention needs to be paid to portfolio project management [14]. However, the IP regime within the sector tends to discourage a more ‘reciprocal’ approach to managing project interdependencies. We explain this with reference to the different sources of power available to those engaged in biomedical innovation (cf. Hardy and Phillips, 1998) [14] [5] and have also explored the ways in which boundaries across domains of practice/interest may be bridged [13].

5. Activities
The research team has engaged in a wide range of publishing, conference and networking activities - with international scope and impact - which have involved full engagement with academics and practitioners in the UK, US and elsewhere (see Appendix 4).

**Academic activities** include 4 workshops organised (2 in Boston and 2 in Warwick) involving leading academics from the US (MIT) and the UK (Imperial, Manchester). The interactive innovation agenda has also been promoted via the organization by research team members of 2 international conferences in the *Organisational Learning, Knowledge and Capabilities* series, leading to special issues of *EJIS* and *Management Learning*. Presentations have been given at over 25 workshops or seminars – including 4 conference keynotes and invited presentations at numerous international venues (Boston, Chicago, Lund, Linkoping, Copenhagen, Oslo, Dublin). Other activities include the publications and international conference presentations detailed under Section 6 below (and listed in Appendix 4).

A commitment to ‘engaged scholarship’ (Van de Ven, 2007) with practitioners and policy-makers was a crucial component of the research design (**Objective 4**) and its governance mechanisms (via SABs). As well as presentations given at the 5 SAB meetings held during the course of the research, 8 further workshops were held at which our findings were presented to, and discussed with, the practitioner community. These included:

- a public seminar on *Selling Science* joint with the Cambridge-MIT Centre for Competitiveness and Innovation (CCI) and sponsored by East of England Development Agency and Cambridge Science Park (42 delegates from regional development agencies, local industry and local health centres);
- a 2-day international SAB held at MIT, Broad Institute & MIT/Harvard Centre for Biomedical Innovation (day 1) and The British Consulate, Boston (day 2)
- a public panel on *Managing Clinical Trials* (30 delegates including biotechnology industry representatives – Boston, British Consulate);
- presentations at 2 public EBK Programme meetings and at the EBK Final Conference (120 delegates including cross-industry sectors and policy makers);
- a workshop on *Networked Innovation* funded by AIM/IKON at Coventry University
- a workshop at the invitation of Madan Science Park (Portugal).

Half-day workshops were also held with 4 case company partners who chose to have feedback presentations.

### 6. Outputs

**Academic publications** have, to date, amounted to 6 refereed journal articles accepted with a further 4 under review with leading journals (2 on their 2nd revision). 6 book chapters have been published or accepted.

Reported in [1] [2] [7] [15] and [16] are the major findings from the research regarding:

- the multi-level framework and taxonomy (**Objective 3**);
- national institutional differences and their implications for policy and management (**Objectives 1 and 4**);
• the relationship between sectoral systems of innovation and behaviour at the level of
the firm (Objective 2).

Other papers have focused on specific themes arising from the research, namely:

• the unintended effects of UK policy initiatives, specifically Genetics Knowledge
Parks [3];
• the politics of networked innovation, professional power and discourse [5];
• the role of boundary objects in biomedical innovation [13];
• project management processes and biomedical innovation projects [4] [6] [14].

Appendix 2 cross-references specific papers to each of the hypotheses and major
research objectives.

Conference papers have been presented at 16 international and national conferences
and workshops, including:

• Academy of Management (New Orleans 2004, Atlanta 2006)
• Critical Management Studies (Cambridge 2005)
• OKLC/OLKC (Boston 2005, Warwick 2006)
• International Conference in Systems Sciences (Kauai 2006)

A further 8 papers have been submitted/accepted for conferences in 2007.

Case Reports Each of the 10 focal business case partners (listed in the report form)
received a Case Report (approx 5000 word plus summary), together with a cross-case
General Report (15,000 wd/40 page plus executive summary also distributed to/validated
by SAB members).

7. Impacts

Scientific and Health Professionals have begun to benefit from the research through
the project’s SAB. SABs were identified in the research as a key mechanism enabling the
translation of scientific knowledge into commercial development (and one that is less
well used in the UK). Our SAB has helped to ensure, not only that the design of the
research has been sensitive to sectoral conditions, but also that the findings directly
impact upon policy and practice through engagement with opinion leaders in the wider
community of scholars, practitioners and policy makers.

Whilst the impact of this mechanism is difficult to measure, proxy indicators include: (i)
the continued involvement of UK and US Advisory Board members, including their
commitment to an intensive 2 day final SAB in the US; (ii) extremely positive feedback
received from the final SAB meeting (available on request); (iii) the British Consulate Life
Sciences Division’s invitation to host our final workshop at their premises in Boston,
together with a public panel on Managing Clinical Trials; (iv) cooperation from MIT, the
Broad Institute and MIT/Harvard Biomedical Centre in hosting the final workshop; (v)
continued commitment of case study partners; and (vi) invitations to conduct further
collaborative research with SAB members (detailed below).
Public policy makers will benefit from greater insights into how to (and how not to) generate policy aimed at encouraging biomedical innovation. For example, our findings indicate that initiatives such as GKPs are often under-funded and/or too short term to have any significant impact [3]. Institutional differences highlighted in our research also suggest that UK policy cannot simply mimic that of the US. Policy aimed at knowledge transfer by ‘bridging’ professional groups (e.g. network funding) is unlikely to be effective unless mechanisms are also in place to ‘bond’ professional values and practices [2] [16]. Findings on the GKP initiative and policy implications have been reported to UK GKP Directors and the DH.

Industrial impact. The level of industry participation in the research amongst leading biotechnology firms in the UK and US has been high. It is extremely difficult to maintain contact for longitudinal social science research in this very high risk, intensely competitive, information sensitive and transient sector. Collaborators all received a general report on the research, a company specific case history (with lessons learnt) and, in 4 of the 10 organizations, a half-day workshop to present and discuss the findings – from which feedback was very positive. The firms also had the opportunity to reflect on their own innovation processes during the course of the research. Whilst the impact of this is hard to measure, the fact that 10 case companies were continually involved over 2 years, together with the positive feedback received, point to the research being seen as having considerable value.
LIST OF ANNEXES

Appendix 1: References used in full report

Appendix 2: Hypotheses (linked to specific outputs)

Appendix 3: Scientific Advisory Board Membership

Appendix 4: Research Outputs (as of 28th February 2007)
Appendix 1: References Used in Full Report


Appendix 2: Hypotheses (linked to specific outputs)

12 hypotheses were proposed in the proposal to support three of the four major research objectives. The outcomes are presented here by cross-referencing to specific journal articles which have already been published/accepted or are currently under review (see Appendix 4):

_Hypothesis 1: The more numerous and diverse the communities and networks involved in interactive innovation in the biomedical domain, the higher the potential for integrated knowledge to lead to radical innovation, but the more barriers there will be to integrating knowledge across these communities and networks._

This hypothesis relates specifically to objective 2. The hypothesis was supported and the analysis and discussion can be found in [1] [14] [15]

_Hypothesis 2: Diverse epistemic cultures will have different accepted methods for creating and legitimating of knowledge and these may act as barriers to the ability to integrate knowledge through interactive innovation processes._

This hypothesis relates specifically to objective 2. The hypothesis was supported and analysis and discussion can be found in [1] [3] [7] [9] and [13]

_Hypothesis 3: Formal and informal structural and social mechanisms that facilitate the integration of knowledge will vary across and be contingent upon different institutional contexts._

This hypothesis relates specifically to objectives 1 and 2. The hypothesis was supported and analysis and discussion can be found in [1] and [2]

_Hypothesis 4: The integration of knowledge via interactive innovation processes will be influenced by the dynamics of network formation and development which, in turn, will be shaped by the institutional context in which a network is operating._

This hypothesis relates specifically to objectives 1 and 2. The hypothesis was supported and analyses can be found in [2] and [3].

_Hypothesis 5: National institutional differences will have important influences on the ways in which biomedical knowledge is developed in meso-level interactive innovation settings in the UK and US._

This hypothesis relates specifically to objectives 1 and 2. The hypothesis was supported and analysis and discussion can be found in [2] [7] and [16].
**Hypothesis 6:** The ability to develop biomedical knowledge through interactive innovation will depend on the availability of appropriate integrative and relational capabilities

This hypothesis relates specifically to objectives 1 and 2. The hypothesis is supported and analysis and discussion can be found in [1].

**Hypothesis 7:** Integrative and relational capabilities are stronger in the US than in the UK and therefore are likely to facilitate the development of biomedical knowledge in interactive innovation in the US as compared to the UK, although this will depend upon the nature of the specific coordinating mechanisms in place

This hypothesis relates specifically to objective 1. The hypothesis was supported and analysis and discussion can be found in [1].

**Hypothesis 8:** Knowledge is more likely to be developed and legitimated across the constituent communities involved where the interactive innovation forums involve ‘key scientists’ that are able to bridge distinctive networks (e.g. of science and technology) and where inter-institutional ties are present (e.g. through sponsored joint research, scientific advisory boards or licensing arrangements

This hypothesis relates specifically to objectives 1 and 2. The hypothesis was supported and analysis and discussion can be found in [1] and [2].

**Hypothesis 9:** Institutional arrangements governing access to technology are likely to shape the development of interactive innovation processes in different ways across the US and UK and these differences may depend upon the particular areas of science concerned

This hypothesis relates specifically to objective 1. The concentration of cases in certain scientific domains (e.g. tissue engineering) meant that it was difficult to explore this hypothesis fully. However, the results that relate to differences in the dynamics of institutional development within this particular domain do lend some support to the idea that the particular areas of science concerned may be important. Further analysis and discussion can be found in [15].

**Hypothesis 10:** The availability and access to venture capital in the US promotes the development of integrative and relational capabilities necessary to exploit scientific breakthroughs in the biomedical sector to a greater extent than the UK venture capital market

This hypothesis relates specifically to objective 1. The hypothesis received qualified support, in that there is a major gap in early stage funding in both the UK and the US. Analysis and discussion can be found in [2].
**Hypothesis 11:** Problems in the supply and coordination of personnel and differences in career and incentive systems may militate against involvement of key scientists and medical professionals in interactive innovation in the biomedical area in the UK as compared to the US

This hypothesis relates specifically to objective 1. The hypothesis was supported and analyses can be found in [2].

**Hypothesis 12:** Increasing government intervention in the US and UK healthcare systems will effect the development of radical innovations in biomedicine

This hypothesis specifically relates to objective 1. The hypothesis received qualified support, in that the results suggested that UK government intervention policies would need to go beyond the various ‘bridging’ mechanisms currently developed. Analysis and discussion can be found in [3].
Appendix 3: Scientific Advisory Board Membership

UK Advisory Board Members:

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Appendix 4: Research Outputs (as of 28th February 2007)

Refereed Journal Papers


Book Chapters


Papers Submitted to Journals (and under review)


Books/ Edited Works


[18] Newell, S., Robertson, M., Scarbrough, H. and Swan, J. Managing Knowledge in Organizations. Contract with Palgrave (due June 2008) to include case studies from current project.

Papers Presented at Conferences


REFERENCE No. RES-334-25-0005


Papers Submitted/Accepted at Conferences


**Workshops Organized by Project (and Presented at)**


[44] Imperial Tissue Engineering and Regenerative Medicine Centre/ Novathera, Practitioner Workshop presenting final project findings (half day), 6 December 2006

[45] Obembe, A. and Swan, J. Academic/Practitioner Workshop *From Innovation to Mainstream Healthcare: Addressing the Challenges of Translation*, in collaboration with Centre for Research on Innovation and Creativity (University of Manchester) and Imperial College (full day), 29 Nov 2006.

[46] Nowgen Genetics Knowledge Park, Practitioner Workshop presenting final project findings (half day), 15 November 2006

[47] International UK/US Scientific Advisory Board Workshop (two full days), Sept 28/29th 2006, held at Massachusetts Institute of Technology, Broad Institute & MIT/Harvard Centre for Biomedical Innovation (day 1) and The British Consulate, Boston (day 2)


[49] Peptimmune, Practitioner Workshop presenting final project findings (half day), September 26th, 2006

[50] Organogenesis, Practitioner Workshop presenting final project findings (half day), September 25th, 2006

[51] Newell, S. and Swan, J. Workshop on *Exploring Innovation Processes in Healthcare: The challenges of collaboration and governance* (full day), Bentley College, USA, May 18th 2006
US Scientific Advisory board Workshop (full day), Bentley College, Boston, USA, October 2005

UK Scientific Advisory Board Workshop, (full day), Warwick University, July 2005


Knowledge and Innovation Network (KIN) Practitioner workshop on Innovation and Networks (full day), University of Warwick, June 2005.

US Scientific Advisory board Workshop (full day), Bentley College, Boston, USA, September 2004

UK Scientific Advisory Board Workshop (full day), Warwick University, UK, June 2004

Swan, J., Robertson, M., Perkmann M. (2 full days) Workshop on Innovation and Networks, Presented for Madan Science Park, Universidade Nova de Lisboa, Portugal, June 2004

Robertson, M. and Swan J. (half day) The role of interactive innovation in the evolution of genetic knowledge, ESRC Seminar Series: Cultures of the gene: Dialogues and debate, Institute of Health, University of Warwick May 2004

One day project launch workshop The Evolution of Business Knowledge: Interactive Innovation in the UK and US, Bentley College, Boston, May 2003

Conference Organization

Robertson, M. and Swan, J. Organizers (with Scarbrough and Nicolini) of 2006 International Conference on Organizational Learning Knowledge and Capabilities, University of Warwick, March 2006 (180 delegates plus doctoral workshop with 26 students)

Newell, S. Organizer of 2005 International Conference on Organizational Knowledge, Learning and Capabilities, Boston, USA March 2005 (160 delegates plus doctoral workshop with 30 students)


Keynotes


Other Invited Presentations & Seminars

Robertson, M. Networked innovation and the evolution of biomedical knowledge Networked Innovation – Developing a Future Research, AIM Capacity Building Workshop, Coventry University Techno Centre, February, 2007


Newell, S. Interactive Innovation in the UK and US. Boston University Health Services Group, October 2006


Swan, J. The Evolution of Biomedical Knowledge: Interactive innovation in the UK and US. Warwick Innovative Manufacturing Research Centre, Phase 1 Final Conference, University of Warwick, July, 2006


Robertson, M. and Swan, J. The Evolution of Biomedical Knowledge: Interactive innovation in the UK and US. EBK Advisory Board Meeting, Dec 2005
REFERENCE No. RES-334-25-0005

[81] Swan, J. Why do (and don’t) organizations learn from projects? Birmingham Business School Seminar Series, UK Nov 2005

[82] Scarbrough, H. and Swan, J. Why do (and don’t) organizations learn from projects? Invited seminar for Freeman Centre Seminar Series, University of Sussex, July 2005


[84] Invited Roundtable on Project Organizing at Linkoping University, Sweden, April 2005

[85] Swan, J. The problem of biomedical innovation projects. Lund University, Sweden, April 2005

[86] Swan, J. Critical challenges in project-based learning. Norwegian School of Management, Oslo, Norway, April 2005


[88] Presentation on Preliminary findings at Warwick Innovative Manufacturing Centre Seminar, March, 2005.


[91] Scarbrough, H. and Swan, J. Why don’t organizations learn from projects? Bentley College, Boston, Nov 2004


[93] Bresnen, M. Project-based work and organisational learning, Doctoral School of Organisational Learning, Danish University of Education, Copenhagen, Nov 2004


Reports


**Additional Funding/Research**

[99] Anna Goussevskaia secured funding to allow comparative analysis with a parallel project in Brazil, following the research design for this EBK project. Brazil has a large, rapidly expanding biotechnology market and is a major centre for health biotechnology. Resources provided for: fieldwork nationwide, dedicated research fellow, 2 part-time RAs and infrastructural support. The project is based at Fundação Dom Cabral (http://www.fdc.org.br/en/default.asp) – a reputable business school in executive education in Latin America, which has strong links with biotech industry and major pharma companies.

[100] An extension to the work on this project involves collaboration with Dr Sue Dopson (Oxford University) and the UK Genetics Knowledge Parks to conduct research interviews in all 6 UK GKPs, focusing on the management, organization and governance of GKPs and the impact of public policy on the GKP initiative.

[101] Additional RCUK/WBS funding was secured for an RCUK Fellow (Davide Nicolini) to join IKON to conduct directly related research on exploiting innovation in healthcare.

[102] Additional funding (value £10,321) secured from the Warwick Innovative Manufacturing Research Centre (WIMRC) to conduct an 8-month ethnographic analysis of a particular case of bioreactor innovation in Imperial’s Tissue Engineering and Regenerative Medicine Centre (one of our case sites). This extends the larger project by adding a micro-level, practice-based study of knowledge integration amongst scientists engaged in laboratory work (PIs Nicolini and Swan).

[103] Doctoral studentships (£10,000 p.a.) have been secured from the IKON’s practitioner-based Knowledge and Innovation Network (KIN) to support comparative studies with the biomedical sector as a major area.