

# Genomics as a new innovation regime. Towards a research agenda

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## **Abstract**

Out of the research field of clinical genetics, medical genomics is developing as an international research field characterised by large-scale consortia, the use of high throughput technologies, strategic public investments, public-private relationships, and large genetic databases serving as links between academic and commercial interests. Our research aims at understanding this development as a transformation of 'innovation regime'. Innovation regimes comprise the rules for coordination in innovation networks. Innovation networks are heterogeneous networks organised around four distinct poles: science, industry, clinic and regulation. These concepts are used as a heuristic to organize and make sense of insights from existing literature and to guide semi-open interviews. In addition, the conceptual framework allows us to focus on some aspects of the regime transformation that can be studied with a more hypothesis-driven approach. This paper proposes a number of research strategies for the latter.

## **Introduction**

In the past decades we have witnessed some remarkable changes in the field of human genetics. In the 1980s and 1990s, networks of research scientists, clinicians, charities and other funding bodies based around hospitals have been pivotal in the creation of genetic knowledge and its introduction in clinical practice. In the Netherlands for example, regional clinical genetics centres have developed as nodes linking genetic laboratory research and diagnosis with clinical patient care and counselling. A distinctive feature of this cooperation is the strong orientation of human genetics research to clinically relevant genetic diseases, whereby patient associations often play an important role as intermediaries in supporting research and establishing contacts between patient populations and the scientific community (Nelis 1998; Stemerding 1993). The evolution of cytogenetics in the British National Health Service has been described in similar terms as a history which reveals a 'hidden research system' embodied in a national network of laboratories and clinics, with close cooperation between researchers and clinicians (Hopkins 2004; Hopkins 2006).

With the rise of genomics as a new research field we see, in the field of human genetics, significant changes both in the agenda and the organisation of research. Research is now developing in the context of large-scale consortia, characterised by international, multidisciplinary collaboration, use of high throughput technologies, strategic public investments and public-private relationships. In the literature this transformation has been described as the emergence of a new type of research system in the domain of human genetics, forming the centre of an emerging market for personal and population-based genetic information. In this system large genetic databases are created as platforms which not only facilitate large-scale studies of the role of genetic and environmental risk factors in the development of common diseases, but also serve as nodes in new emerging research networks linking academic and commercial interests in the field of human genetics (Martin 2001; Williams-Jones and Graham 2003).

The main thrust of our research is to understand these changes as a transformation of 'innovation regime' comprising a new agenda, the use of improved technologies, new roles for existing actors, new actors, changing divisions of labour, new policy frameworks, and hence changing configurations

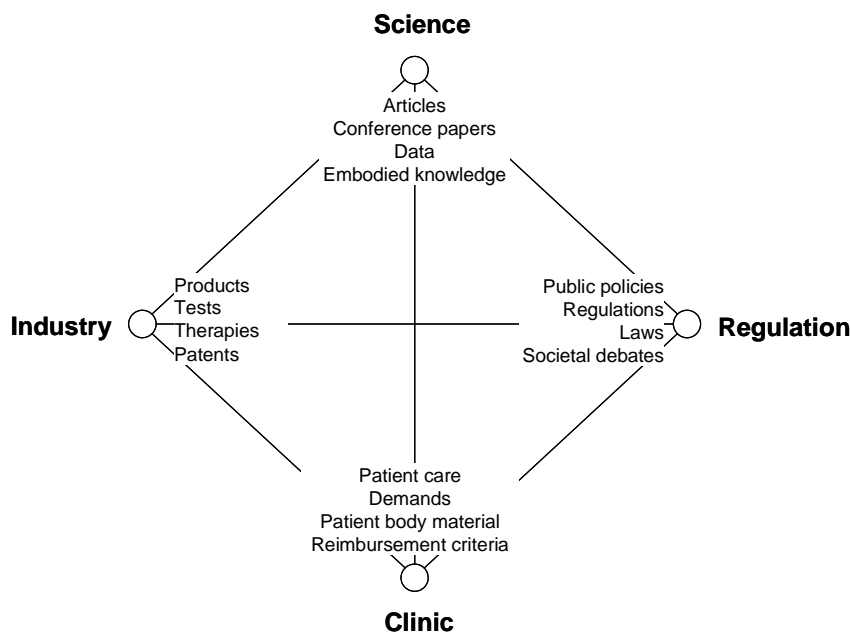
of networks. This paper reports the first step in our research: a conceptualisation of this innovation regime, a specification of the main hypothesis of a regime transformation, and a proposal for indicators to use in the research.

## ***Innovation regimes and innovation networks***

The notion of an innovation regime refers to complexes of coordination rules on how to act and interact in innovation networks, which are institutionalised at an interorganisational level. Innovation regimes attribute responsibilities to actors and thus imply particular interdependencies and divisions of labour between actors. An innovation regime thus enables and constrains activities in an innovation network. An innovation network is defined as a *coordinated* set of heterogeneous actors - research institutes and universities, hospital clinics, firms, regulatory bodies and patients - which participate collectively in the development and diffusion of innovations, and which via many interactions organise the relationships between scientific research, technology development, and clinical practice.

Networks are organised around poles, which are characterised by the kinds of objects which actors in different network positions produce and exchange (figure 1). Drawing on the techno-economic network approach (Callon et al. 1992; Callon 1991), we distinguish four main poles and three intermediary poles. On the science pole scientists and researchers produce certified knowledge in the form of articles and embodied knowledge. On the industry pole, corporate researchers and engineers participate in technology development by writing patents, developing models and prototypes. On the clinical pole are the clinicians, patients, patient groups and reimbursement agencies, who articulate and specify needs and buy products, thus economically value products. On the regulation pole are actors professionally occupied with the regulation of research and innovation. We see regulation as a set of interventions that find their legitimacy in broader policy discourses, but at the same time as influenced by and responding to developments in the innovation regime.

In addition to these four main poles three intermediary poles are distinguished. A knowledge transfer pole is characterised by services to stimulate the use of certified knowledge for product development and vice versa the use of technological instruments for scientific purposes. Within a commercialisation pole firms and public agencies are engaged in marketing, promotion and monitoring activities to stimulate the interaction between users and producers of technology. This intermediary pole comprises the market for diagnostic tests and pharmaceuticals. A clinical research pole, finally, refers to the collaborations between researchers and clinicians in ‘hidden research system’ of hospitals and clinical genetics centres (Hopkins 2004; Hopkins 2006). Also the development of biobanks based on clinical information and scientific knowledge is an important activity on this pole.



**figure 1. The poles of innovation networks. Intermediary poles are left out of the picture to avoid complexity**

## ***Towards a research agenda***

The concepts of innovation regimes and innovation networks are used as a heuristic to organize and make sense of insights from existing literature and to guide semi-open interviews. There is an overall story, which is complex due to many interrelated developments pertaining to various practices and levels. An explorative approach is adopted to gain a comprehensive understanding of these developments as a regime transformation. In addition, the conceptual framework allows us to focus on some aspects of the regime transformation that can be studied with a more hypothesis-driven approach. The rest of the paper deals with the relation between these approaches focusing on developments on the main poles.

### *Developments on the science pole*

Interviews learn that the most remarkable development on the science pole of the networks is a shift from monogenetic diseases to multifactorial diseases and a related shift from hypothesis-driven research to association studies, characterised by their more inductive strategy. Reasons mentioned are the complexity of causes and correlations, the possibility to use faster technologies and the hence the availability of more data.

Whether this shift in agenda and method are getting a foothold can be studied in more detail by tracing emerging irreversibilities (Van Merkerk and Robinson 2006). This approach takes a keyword and assumes that irreversibility emerges when this keyword is first only used in the context of expectations and visions, later in the context of agenda statements and finally in the context of networks. Networks are likely to include experts in bio-informatics. An appropriate keyword is ‘association study’.<sup>1</sup>

### *Developments on clinical pole*

Whereas genetic research was initially mainly relevant in the field of clinical genetics, we see that genomics approaches and DNA technology are increasingly used in other medical disciplines, such as oncology, rheumatism and asthma research.

With the same emerging irreversibilities approach one could study this development. Keywords indicating this new orientation (e.g. genomics/genetics/microarray) are assumed to figure in the context of first expectation statements, then agenda statements and finally network statements in journals and textbooks used in these fields.

### *Developments on the industry pole*

Three trends on the industry pole are a growing interest of pharmaceutical companies in genomics research and biobanks, the rise of small dedicated biotechnology firms in the sector, and an increase of patents owned by academic scientists. These trends indicate convergence between science and industry and increased incentives to collaborate in innovation networks.

These trends can be studied by measuring industry sponsored biobank developments and industry sponsored clinical research projects into biotechnology based therapies (or alternatively using the emerging irreversibilities approach in application oriented journals like Drug Discovery), the number and investments of biotechnology firms collaborating in innovation networks, and the number of patents owned by academic researchers relative to publications.

### *Developments on the regulation pole*

Via the Netherlands Genomics Initiative (NGI), the Dutch government’s key return expected from genomics research is knowledge valorisation. The NGI has set quantified valorisation targets for genomics consortia (dissertations, patents, start-up companies, industrial matching). These, together with roles for private parties and TTOs, are described in ‘valorisation plans’ of consortia. Valorisation is a mode of governance of the relation between science and industry. This focus on valorisation

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<sup>1</sup> We select the Leiden Center for Human and Clinical Genetics as a case, because this center has been strongly involved in both regimes during the period of investigation. The case comprises the networks this center has been involved in over time. The sample for studying emerging irreversibilities on the science pole accordingly consists of publications by this center.

might, however, have gone at the expense of the governance and institutionalization of other labor divisions in the new innovation regime, such as the institutionalization of research and links necessary for the construction of high-quality biobanks and of links required for effective translation of technology into clinically relevant applications.

The preferred strategy here is to reconstruct the valorisation debate and trace the power struggles that have led to the particularly economic interpretation of valorisation. It is, however, important not only to focus on genomics policy and the NGI, but also on related policies and funding schemes that may have an impact on the division of labour in the innovation networks. This is because the links that are required for, for example, biobank development or the effective translation from industry to clinic may have been supported by policies with a broader focus or may be evaluated as not in need of government support.

Similar research strategies should be developed for the study of trends on the intermediary poles, especially because many of these trends are indicative for the transformation of the innovation regime. On the knowledge transfer pole, the role of Technology Transfer Offices is noteworthy as well as the increase of corporate research and the number of collaborations between scientists and firms in genomics consortia. On the clinical research pole the formation of links between genomics researchers and medical specialists other than clinical geneticists is indicative, especially those links that are established to construct high-quality biobanks covering a broad range of variables. On the commercialisation pole, the relations between these medical specialists and the pharmaceutical industry should be better understood. This is especially important to understand how genomics research becomes clinically relevant via the industrial route, whereas in the clinical genetics regime research results were often made directly relevant for the clinic.

The overall objective of this research is to understand how the transformation of innovation regimes involves a new division of labour and responsibilities between actors on the various poles of networks. This has important implications for governance. Governance is conceived of as the facilitation of innovation via infrastructures and institutions in which these labour divisions get embedded. The evaluative question is whether the current governance regime adequately accommodates all labour divisions required for convergent innovation networks.

A second objective of the research is to explain the new division of responsibilities from a multilevel perspective. Whereas some developments within innovation networks trigger each other, some other developments may have risen from broader trends in society. An example is the more general shift on the academic research system towards economic relevance, exerting pressure on scientists to apply for patents. The conception of innovation networks as organised around poles serves as a heuristic for a multilevel approach if the poles are themselves seen as historically punctuated networks with their own rules and conventions (Callon 1991; Rip and Schot 2002). A multilevel approach furthermore enables comparison of the dynamics of this regime transformation with others, such as is agricultural biotechnology.

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