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Systems biology: A disruptive biopharmaceutical research paradigm

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Abstract

Since the completion of the Human Genome Project a new biological paradigm has emerged, namely systems biology. This paradigm is advancing the view that biology is essentially an information science with information operating on multiple hierarchical levels and in complex networks. A new hierarchical framework for biological knowledge is being constructed to understand the relationships between the various levels of information. Although the goal of finding new medicinal entities is central to drug discovery, the search itself has been dramatically altered in the post Human Genome era.

It is our view that systems biology is a disruptive biopharmaceutical research paradigm. Biopharmaceutical knowledge production processes, knowledge dissemination processes, and even knowledge appropriation mechanisms are rapidly evolving to maximize value creation during drug discovery and development. A knowledge framework is used in this paper for conceptualizing and enabling the efficient management of these new complexities in systems biology. Fundamentally important to medical progress is ensuring that multiple innovators can equitably exploit the technological opportunities presented by systems biology. We evaluate the role of academia, government, and industry in preserving these technological opportunities.

Keywords: Systems Biology; Research Paradigms; Knowledge Management; Intellectual Property; Research Policy

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1. Introduction

A new biological paradigm, systems biology, has emerged with the completion of the Human Genome Project. Systems biology aims to develop a systems-level understanding of biological processes. The Human Genome Project has advanced the view that biological information operates on multiple hierarchical levels and is processed in complex networks [1]. It is no longer sufficient to develop a biological model and perform analyses at only one or two levels of biological information. What is required is an understanding of the behavior of molecules within a system and as a function of the characteristics of the system. Biological systems will be understood within a framework of knowledge that is built up from the molecular level to the organism level [2].

System biology knowledge is complex and derives from a variety of scientific and technical disciplines. Progress in genomics, proteomics, computational sciences, and measurement technologies will enable the understanding of biological systems. New analysis techniques, experimental methods, measurement technologies, and software tools will be developed to assist in the experimental decomposition and then *in silico* (computational) composition of systems [3]. The various interactions between genes and proteins, the mechanisms by which such interactions modulate the structures of a cell, the behavior of systems in normal and disease states, the modulation of systems to minimize malfunctions, and the ability to redesign systems, must be understood to obtain deep insight into biological systems. In this paradigm, the biologist can no longer work in isolation. Collaboration between various disciplines is required as the drug discovery process evolves to incorporate this new paradigm. Networks of collaboration that are supported by information and communication technologies will enable researchers from a variety of disciplines and laboratories to generate and validate systems biology knowledge. The structure and rules associated with systems biology-based networks will support the global production and dissemination of knowledge.

It is our view that the systems biology paradigm is a disruptive biopharmaceutical research paradigm. Although the goal of finding new medicinal entities is central to drug discovery, the search itself has been dramatically altered in the post Human Genome era. The molecular level of analysis, the computational nature of discovery research, and the global scale of research support our claim that systems biology is a disruptive paradigm. From a knowledge perspective, biopharmaceutical knowledge production processes, knowledge dissemination processes, and even knowledge appropriation mechanisms are rapidly evolving with the emergence of this paradigm.

We develop a knowledge framework in this paper to understand the disruptive nature of the systems biology paradigm from each of these perspectives. We begin with a discussion of the reorganization of early systems-based discovery research to enable cooperative knowledge production. We then discuss how in systems biology, knowledge production and dissemination processes must take into account that knowledge is varied in form and function. Knowledge must be produced in a manner that is efficient and cohesive. Furthermore, knowledge must be codified through the use of standards to meet the needs of researchers functioning across multiple scientific and technical disciplines. Once produced, each scientific or technical field will have its own conventions regarding knowledge appropriation. These conventions may not be identical or stable and it cannot be assumed that the conventions of all members will converge simply through the creation of a cross-disciplinary organizational structure [4]. Measures and signals of success in knowledge generation activities will instead determine the value placed on this knowledge by the various disciplines. Therefore, we discuss that increasingly, the characteristics associated with systems biology knowledge will determine the timing of knowledge appropriation. As accessibility may be