

Original Research

Evolution of Business Models in Regenerative Medicine: Effects of a Disruptive Innovation on the Innovation Ecosystem



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ABSTRACT

Purpose: This article focuses on 10 case studies of companies/organizations that are part of the current innovation ecosystem of regenerative medicine (RM) in the United Kingdom. It analyzes the actors, linkages, and influences that will determine the future shape of the RM industry sector and its capacity to live up to its initial expectations.

Methods: Using the case study approach, purposive sampling was used to get 18 interview respondents from 10 RM companies/organizations in the United Kingdom. We used semistructured interviews for data gathering and thematic analysis for identifying gaps in the RM value chain (ie, the range of activities required for bringing a product from conception to market and end-use) and the influences of the innovation ecosystem on the evolving RM business models.

Findings: RM promises to address currently unmet health care needs by restoring the normal form and function of cells, tissues, and organs. The innovations emerging to support the progress of RM to satisfy these important health care markets will disrupt the business models of incumbent industry sectors, particularly pharmaceuticals. Companies involved in this area must develop innovative business models and value chains and negotiate the complex influences of the innovation ecosystem, including regulatory systems and standards, financial support systems, and new market dynamics.

Implications: This article highlights the needs for more systemic analyses of the needs of potentially disruptive innovations, in RM and more widely, and for policymakers to give greater attention to these insights in planning regulatory and other supporting initiatives, with the promotion of innovation in mind. (*Clin Ther.* 2018;40:1084–1094) © 2018 The Authors. Published by

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Key words: business models, regenerative medicine, United Kingdom, disruptive innovation, innovation ecosystems.

INTRODUCTION

Regenerative medicine (RM) is a disruptive innovation set to change therapy for intractable medical conditions. It departs from conventional therapy because of its claim to cure rather than merely treat chronic conditions; and the necessity for new forms of clinical delivery collaborations between therapy manufacturers and surgeons. However, there are concerns that the translation of disruptive RM innovations may be slow or fail to materialize.¹ Gardner et al¹ suggested, "RM products and procedures will have to work very hard to find or create an adoption space if translation into clinic is to be successful." Our article builds on the discussion by Gardner et al¹ of translational challenges in the context of clinical trials; regulatory norms; manufacturing, scale-up, and logistics; reimbursement and commissioning; and clinical adoption. However, we focus on RM business models; gaps in the RM value chain (ie, the range of activities required for bringing a product from conception to market and end-use); and challenges, from the innovation ecosystem, facing the emerging RM business models, in the context of the United Kingdom.

There are 2 important RM therapy categories: (1) *autologous*, in which a patient's own cells are

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harvested; manipulated in a laboratory, factory, or clinical setting; and reintroduced into the same patient; and (2) *allogeneic*, in which different patients receive cells manufactured in a central facility, from a single donor.^{2,3} The choice of autologous or allogeneic therapy is determined by disease area, the availability of therapy, or regulatory pressure on developers.⁴ We argue that accelerating the clinical adoption of RM will depend on an innovation ecosystem that facilitates faster integration of RM and allied business models to form viable value chains,³ aided by proportionate and adaptive governance systems.⁵ Regarding value chain gaps and innovation ecosystem challenges facing RM business models, we accept Faulkner's⁶ assertion that RM is a site for "opposing forces for gatekeeping and innovation." The key to resolving these opposing forces, in keeping with the EU's innovation principle,⁷ is to develop regulatory systems that are more proportionate and adaptive to the needs of new technologies than are those currently in operation, involving more creative use of standards and guidelines.⁸ Downstream, innovation ecosystem challenges need to be resolved, in particular the adoption of RM therapies by clinical practice, as exemplified by the UK government's effort to establish advanced-therapy clinical centers and reimbursement. Mahalatchimy⁹ discussed 2 routes of reimbursement: (1) health technology assessment, for larger-scale disease populations; and (2) highly specialized technology evaluation, for rare diseases (which is more appropriate for many RM therapies).

In this article, we discuss the value chain gaps and innovation ecosystem challenges facing the evolving RM business models in the United Kingdom. The analysis has 3 categories: (1) nonintegrated value chains; (2) technology and delivery models gap; and (3) disproportionate and nonadaptive governance systems. The discussion of each category contains illustrative examples: for nonintegrated value chain, manufacturing gap, clinical adoption gap, and translational services gap; for technology and delivery models gap, different dynamics for autologous and allogeneic therapies, RM logistics issues, and national regulatory and reimbursement systems; and for disproportionate and nonadaptive governance systems, first-mover disadvantages of regulatory learning and costs, and limited patient numbers for clinical trials in small indication.

In the rest of the article, business models, innovation ecosystems, and the framework used by STRATIS (Strategic Planning of Advanced Technological Innovation

Systems) framework are briefly discussed; and findings, a discussion, and conclusions are presented.

MATERIALS AND METHODS

Using the case study approach, purposive sampling was used to get 18 interview respondents from 10 RM companies/organizations in the United Kingdom. We used semistructured interviews for data gathering and thematic analysis for identifying value chain gaps and the influence of the innovation ecosystem on the evolving RM business models.

RESULTS

Regenerative Medicine Business Models and Value Chains

Business models are frameworks of understanding the logic of an enterprise, that is, how it creates and appropriates value from its unique product(s) and service(s) offering(s). A business model describes, "for a sector or sub-sector, how firms operating within it can create, capture and deliver value. It acts as a guide to incumbent and future businesses aiming to increase the amount of value they can create or capture, often through the adoption of innovative technology."⁸ In this article, we use the 6 RM business models (Figure 1) identified by Banda et al (personal communication, [2018]), defined as follows:

- **Materials and service provision business model.** These firms or organizations supply raw materials, reagents, machinery, and other equipment and quality-assurance services to RM firms/organizations. They derive value from offering services and products for RM activities spanning preclinical, efficacy, and tolerability testing.
- **Early exit Phase I/II business model.** These firms or organizations focus on the early stages of development of RM therapy. They capture intellectual property after developing innovative products, processes, and platform technologies. They appropriate value by progressing therapies to proof-of-concept or Phase I/II clinical trials or trials demonstrating efficacy and tolerability, and exit the RM value chain by selling off intellectual property or technology to more resourced firms, for example "big pharma."
- **Manufacturing and scale-up business model.** These firms or organizations specialize in investing in current Good Manufacturing Practice (cGMP)-compliant plants and contract manufacture therapies for other RM firms. They also assist other firms in developing

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