



Ethics, Innovation and Entrepreneurship in Biotechnology - A Systematic Review of Moral Boundaries and Entrepreneurial Decision- Making

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Abstract

The area of biotechnology entrepreneurship is unique due to its high levels of both technical and economic uncertainty; and an elevated level of ethical awareness and concerns. Advances in genomics, gene therapy, synthetic biology, and data driven life sciences present biotech entrepreneurs with new and difficult to address ethical issues which are not limited to compliance with regulations but will influence their entrepreneurial decisions and the paths they take for innovations. While there has been extensive research on ethics and entrepreneurship separately, very little research exists on how ethics influences the decisions of biotech entrepreneurs and the paths they follow to create innovations in their biotech ventures. This paper provides a systematic review of scholarly research focusing on the relationship between ethics, innovation, and entrepreneurship in the biotechnology and life sciences industries. Using a combination of peer reviewed journals, policy reports and case studies published from 2015-2024 the systematic review identifies and integrates common themes regarding: (1) the process of establishing boundaries of morality; (2) how regulation impacts entrepreneurial behaviors; (3) how funding influences ethical considerations; and (4) how entrepreneurs can implement practices to promote responsible innovation. The results of the systematic review indicated that ethics, when considered as part of an entrepreneurial venture, may serve to constrain, shape an entrepreneur's identity, and provide strategic direction for a biotech entrepreneur.

Keywords: Biotechnology Entrepreneurship, Ethics of Innovation, Life Sciences, Moral Boundaries, Responsible Innovation



1. Introduction

The rapid growth of new ventures in the field of biotechnology has created an explosion of innovative opportunities for entrepreneurs in the areas of health care, agriculture and environmental sustainability; these opportunities have included new and innovative medical treatments, diagnostic methods and technologies that can transform many aspects of our lives.

At the same time, as biotechnology innovations interact with living organisms (plants, animals), DNA, and other sensitive types of data, it is becoming increasingly clear to government regulators, financial investors, and societal stakeholders that there will be significant and intense scrutiny by ethics experts for all biotechnology-related innovations.

Historically, much of what we have learned about entrepreneurship has been based on theories related to opportunity recognition, the process of commercializing products, and measuring the performance of a new venture. While there is a growing body of literature that addresses the ethics of entrepreneurship, most of this work focuses on how new ventures comply with regulations or implement socially responsible business practices.

This study aims to review and synthesize existing studies that fall under the rubric of ethics, innovation and entrepreneurship in biotechnology. In so doing, it aims to address three major objectives. First, it will attempt to explore the ways in which entrepreneurs in the biotech industry conceptualize moral boundaries in the context of innovation. Second, it will attempt to understand how entrepreneurs in the biotech industry navigate the ethical issues that arise when making decisions with regard to the development and implementation of new technologies. Third, it will seek to identify the gaps in the existing body of knowledge in the area of ethics, innovation and entrepreneurship in biotechnology and identify potential areas for future research in this area.

2. Review Methodology

To provide a level of methodological rigor and to be transparent in the selection process a systematic literature review approach was used to select relevant studies. This involved searching academic databases (i.e., Scopus, Web of Science, JSTOR, Google Scholar) with combinations of keywords related to biotech entrepreneurship, ethics of innovation, life science startup companies, the ethics of establishing "moral boundaries" in biotech, and "responsible innovation".

Criteria Used to Select Inclusionary Sources:

- Journal articles and scholarly books that have been peer reviewed
- Articles and books published from 2015 through 2024
- Articles/books addressing some aspect(s) of ethics of biotech, innovation, or entrepreneurship
- Published in English

Criteria Used to Select Exclusionary Sources:

- Non-academic articles or non-scholarly sources



- Articles/books that focus exclusively on clinical bioethics and do not have relevance to entrepreneurship

After conducting an initial review of titles and then reviewing the full texts of the remaining articles/sources, it is estimated that ~45 sources will be analyzed thematically and include: Ethical frameworks; Regulatory environment; Entrepreneurial decision making; Funding mechanisms; Governance structure.

3. Ethical Frameworks in Biotechnology Innovation

Traditional bioethics has always relied on some core principles to guide ethics in biotechnology - for example, respect for autonomy, beneficence, non-maleficence, and justice (Beauchamp & Childress, 2019) - which are used in many forms of institutional review and regulatory oversight in biomedical research studies using human participants.

However, there is also an increased complexity when entrepreneurial biotech companies are developing new products because, among other factors, business objectives, and patent protection, and the competitive marketplace all affect how these businesses will approach their ethical responsibilities, and do so in ways that traditional bioethics cannot completely account for.

Thus, as researchers have noted, many of the ethical issues that influence the development of new technologies are considered early in the development process and will be used to help set the agenda for future research, and to help determine what characteristics of the emerging technology should include (Powell & Sandholtz, 2012). As a result, this can make it difficult to apply the traditional model of innovation that assumes that ethics will be considered after the product or service has already been developed.

In addition, decision-making regarding whether or not to pursue a particular area of research or product development, occurs when the potential risks and benefits associated with the long term implications of those products and/or services, are unclear and therefore require consideration of both known and unknown variables (Powell & Sandholtz, 2012).

4. Entrepreneurship and Moral Boundary Formation

Moral boundaries represent where society draws lines regarding acceptable innovation; thus, they are formed by societal and regulatory norms, culture, science and stakeholders' expectations of biotech entrepreneurs (Jasanoff, 2016). Due to the nature of biotech entrepreneurship, both the boundaries themselves and the amount of certainty and resources available for navigating them are unknown at the inception of most new ventures.

As such, the literature has identified a trend of "ethical anticipation" among biotech entrepreneurs who develop their innovation strategy around anticipated ethical controversy rather than solely in anticipation of future regulatory requirements (Jain & George, 2007). Such anticipatory actions demonstrate an active engagement with moral boundaries and, therefore, illustrate that ethics may affect entrepreneurial agency and not just limit it.



Moral boundaries represent the maximum amount of innovation society will accept and define what is permissible. The boundaries are influenced by the regulatory frameworks of the government, societal/cultural norms of the community where the innovation is being developed and implemented, scientific communities and the expectations of stakeholders (Jasanoff, 2016). Therefore, entrepreneurs must establish and understand the moral boundaries through which they operate, and this occurs within high degrees of uncertainty and limited resources.

There is evidence from previous literature that there is an ethical anticipation pattern that exists among entrepreneurs who base their innovation strategies on anticipated ethical issues related to their innovations rather than simply relying on current regulatory schemes. This anticipatory action demonstrates that entrepreneurs engage actively with moral borders, illustrating that ethics can guide entrepreneurial actions rather than simply limit them.

5. Responsible Innovation and Governance in Biotechnology

Responsible Innovation Frameworks provide for the inclusion of ethical thinking as well as the inclusion of stakeholders and society into the development process of an innovation (Stilgoe et al., 2013) As such, these frameworks are being discussed in policy circles and are part of many publicly funded research initiatives.

In biotech entrepreneurship, however, the implementation of responsible innovation practices is inconsistent with respect to larger companies and government-funded initiatives having implemented formalized governance processes for ethics, while start-ups have limited organizational capacity to implement similar processes. The inequality of ethical accountability across the industry represents a serious concern.

Research indicates that the use of regulation has two possible roles in this context. On one hand, regulation may limit or constrain some forms of innovation, while on the other hand, regulation may require entrepreneurs to critically evaluate their research decisions and risk assessments; thus encouraging more intentional ethical thinking. Thus, the design of governance systems could influence the trajectory of innovation and therefore may be viewed as an encouragement of innovation rather than a limitation of innovation.

The emphasis on the incorporation of social responsibility in the development of new products or services is central to the concept of "responsible innovation". Responsible innovation combines ethical thinking with the need for collaboration among stakeholders and social awareness at all stages of the innovation process (Stilgoe et al., 2013).

6. Identified Research Gaps

Studying each of these issues will help researchers better understand the role of ethics as a dynamic aspect of the practice of entrepreneurship, rather than just a static constraint on the practice of entrepreneurship.

The review also identified four major deficiencies in the literature:



1. There are few empirically-based studies that examine the process of making an ethical decision in early stage biotech start-ups.
2. Most of the literature has given too little attention to the various ways in which culture and region may influence where individuals draw their moral boundaries.
3. Much of the literature has assumed that being compliant with regulations is equivalent to taking responsibility for one's ethics.
4. There have been no longitudinal studies that track the evolution of an entrepreneur's ethical thinking as they move from start-up to established business.

Research into these areas could contribute to developing an understanding of ethics as a living, changing part of entrepreneurial behavior rather than as a set of static restrictions.

7. Conclusion

This systematic review indicates that ethics is an important part of the foundation for biotechnology entrepreneurship; Ethics will shape innovation strategy, funding options, and organizational identity, and ultimately guide entrepreneurs' actions regarding science and society.

The reviewed literature does not view ethics and innovation as competing, but instead presents a more complicated picture of how ethical thinking influences and re-directs entrepreneurial action. The synthesis of knowledge from three bodies of research (bioethics, innovation studies, and entrepreneurship) has provided a new level of integration to our understanding of morally sensitive innovation.

As such, future research on ethics and biotechnology entrepreneurship should focus on empirically investigating ethics-related practice in biotech startup companies, particularly early stage firms and in various institutional settings. Understanding ethics-related practices in biotech start-ups through empirical research is necessary to advance theory and inform policies for the life sciences innovation system.

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