RESEARCH PAPER

Commercialising Smart Drug Delivery Systems: A Business Model Innovation Framework For Bioscience Start-Ups

Joseph, J.J[1]*

[1]*Keck Graduate Institute, Claremont, California, USA*

ABSTRACT

The commercialization of Smart Drug Delivery Systems (SDDS), such as stimuli-responsive nanoparticles, implantable microchips, and AI-integrated biosensors, offers significant potential for advancing personalized medicine. However, emerging bioscience startups face substantial challenges in translating these innovative technologies into market-ready products. This study aims to develop a comprehensive Business Model Innovation Framework to assist SDDS startups in navigating the commercialization process. Through thematic analysis of interviews with five early-stage SDDS startups, the study identifies key barriers, including regulatory uncertainty, high R&D costs, and fragmented value chains, while also uncovering successful strategies employed by startups to overcome these obstacles. The proposed framework integrates market readiness, technology readiness (TRL mapping), business model design, and strategic partnerships, offering a structured approach to align technology with market demands and regulatory requirements. The findings highlight the importance of early regulatory engagement, adaptive business models, and cross-sector partnerships in accelerating commercialization. This framework provides startups with a roadmap to overcome common challenges and successfully bring SDDS technologies to market.

Keywords: Smart Drug Delivery Systems, Business Model Innovation, Commercialization Challenges, Technology Readiness Levels, Bioscience Startups

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INTRODUCTION

Smart Drug Delivery Systems (SDDS) is a breakthrough in the sphere of personalised medicine. These systems such as those involving stimuli-responsive nanoparticles, implantable microchips, and AI-integrated biosensors are more efficient, specific, and controllable in the way in which drugs are administered.[1] SDDS may help mitigate the negative effect of side effects and enhance therapeutic outcomes by ontologically administering the drug to the target site, rather than systematically, which in many cases creates unpleasant side effects.[2,3]

As of 2023, technologies provided by SDDS are gaining more central role of healthcare innovation. Some of the technologies that have great possibilities when it comes to transforming the way the field of medicine provides care to their patients, especially regarding chronic conditions, cancer treatment, and neurological work, are nano particles, biosensors, and AI algorithms.[4] This potential is what would be the hard fought quest to realise and is being most difficult in the industrial world. Regulatory uncertainty, excessive costs of the R&D process, and fragmentation of the value chain present a major challenge to the commercialization process of SDDS research outputs.[5]

The present paper will endeavour to establish one model of how the SDDS technologies will be commercialised by the bioscience start-ups. It will also use the business model innovation concepts such as the Business Model Canvas[6] and Technology Readiness Level (TRL) mapping[7] to come up with a map of the problems that should be solved to advance commercialisation. Such a mix of these tools will assist in filling that scientific advancement/market preparedness bubble in the bioscience sector.

Smart Drug Delivery Systems (SDDS) are a new branch of technologies where the delivery agent is an advanced material that must open to release some known therapeutic agent due to a given biological trigger. The technologies stimulate higher precision in drug delivery and hence, advancing their safety and effectiveness. There are different forms of SDDSs which include: Stimuli-Sensitive Nanoparticle are the types of nanoparticle that react to either internal or external stimuli (pH, temperature, light, or magnetic fields) to deliver the drug at the target site.[3] They can be useful especially in cancer treatment because with a high degree of precision, drugs are released only in the unhealthy tissues thus, lessening the pernicious effects on healthy tissues. Implantable Microchips are the microchips that after being implanted under the skin can dispense drugs in a controlled and programmable way in certain duration of time.[8] The solution is applicable to the management of chronic diseases as well as the delivery of hormones.

The process of commercialising the SDDS technologies is full of challenges particularly in terms of limited resources with start-ups. The barriers can be divided into three major categories. First is regulatory issues. SDDS faces a complicated and lengthy process of getting approval. Regulatory agencies like the FDA and EMA demand a significant amount of clinical trial data as a basis of determining safety and efficacy in the case of new technologies, slowing the process of providing them to the market and making it expensive.[9] In the case of SDDS, in which the technology is new or in the developmental stage,

**Author for Correspondence: jenniferjoseph2050@gmail.com*

regulatory approval may be even more difficult because clear guidelines do not always exist in specific jurisdictions. Moreover, secondly, it demands a lot of financial resources in developing SDDS. The development of clinical trials, technologies, and seeking regulatory permissions of a new drug delivery system make it expensive to introduce a new drug delivery system to the market. A study[10] estimates that the total costs of having a new drug advance through the laboratory all the way to market can be as high as 2 billion dollars with a substantial amount of these expenses originating in clinical testing. Third is the issue of modularisation of the value chain. The commercialisation of SDDS may necessitate the involvement of various stakeholders such as, research institutions, pharmaceutical firms, manufacturing plants and healthcare delivery organisations. Were it not that the existence of these entities lacked coordination, there is a possibility that inefficiencies and delays can be experienced when navigating intellectual property agreements, or securing groups in relation to distribution of partnerships.[4]

The concept of business model innovation is very essential in enabling a bioscience start-up to overcome the challenges of commercialisation. Start-ups will need to have open and dynamic business models that match up both the technological changes and the needs of the market. It is believed that the Business Model Canvas[11] can be effectively used to fulfil this purpose as it helps companies identify their value propositions, customer segments, and revenue streams. Technology Readiness Level (TRL) mapping is a method of characterising the maturity development stage of a technology on a scale between basic research (TRL 1) and full market deployment (TRL 9). To identify the right strategy to commercialise their technology, it is paramount that bioscience start-ups engage in the RL mapping in order to understand what stage of technology they currently have.[12]

Notwithstanding the abundance of the studies concerning the problem of commercialisation of the biomedical technologies, it may be noted that there still is a significant research gap concerning the problems being those of bioscience start-ups in this area but working with the Smart Drug Delivery Systems (SDDS). Although research has been carried out on commercialising traditional pharmaceuticals and medical devices, SDDS that depend on vaccine technology (like nanoparticles and AI-linked biosensors) have their own, unique assumptions, and the literature does not fully consider them. Other studies tend to examine either big companies or general biomedical technology, with the specific challenges of entry in the emergency start-up scene in the SDDS sector being underrepresented. The absence of literature on the start-up ecosystem, particularly, related to the mentioned issue of reintegrating advanced technologies in the delivery of drugs into the market, is one of the major gaps, which the paper aims at closing.

The other big gap is the lack of integration business model innovation and the commercialisation of SDDS. Despite the popular usage of business model frameworks such as the Business Model Canvas[13] in different business sectors, their utilisation especially in the SDDS industry was an under-studied area. There is no clear advice in literature on how to tailor their business model to meet the requirements of the market and technology as well as government regulation related to SDDS start-ups. This research will attempt to fill this gap by proposing a framework that start-ups can utilise to evaluate their business model to adapt it to the needs of the SDDS commercialisation process in particular that has not been accessible in the works which have already been made.

Theoretical Framework

This theoretical framework would have two foundational concepts that the study has used to guide the study by analysing the concept of business model innovation and technology readiness that plays pivotal roles in determining the nature of commercialisation difficulties and solutions that bioscience start-ups face when undertaking Smart Drug Delivery Systems (SDDS). The business modelling approach of Business Model Innovation[11] provides the knowledge base of how start-ups can adjust their business models to suit the desirability in the market and surmount the hindrance to commercialisation. Relevant tools used in this framework include Business Model Canvas[14] which provides a methodical process in determining the value propositions, customer groups, revenues and key allies. Within this framework, the concept of flexibility and adaptability is critical because these are the characteristics of bioscience start-ups operating in open and risk-prone industries, such as SDDS. Also, the Technology Readiness Levels (TRL) [7] are employed to determine the maturity of the technology and its viability to become the object of clinical trials and entry into the market. The TRL scale allows start-ups to make rational decisions regarding the time of the start of the product implementation, as well as attracting investments, so that the technologies they have are in a state when they can receive regulatory permission and step up to the next level. This framework is further complemented by the concept of regulatory and market readiness[15] that can solve the external problems of SDDS start-ups. Due to the absence of uniform regulations focusing on innovative technologies, regulatory uncertainty and the absence of universal regulations are another major obstacle in the bioscience industry, especially when it comes to the emerging drug delivery devices, such as the nanoparticles and the miniaturised implantable microchips. The framework recognises that start-ups must get to know the maturity of the technology as well as the regulatory environment to succeed in the steps of approval. This framework brings business model innovation and technology readiness coupled with regulatory alignment issues to map out a complete commercialisation theory that start-ups can use to fill the gap between scientifically supported innovations and market reception.

2. MATERIALS AND METHODS

The methodology employed in this study is the qualitative case study method. The case study will be used to look at the commercialisation of SDDS by new bioscience enterprises. The chosen start-ups are positioned in North America and Asia and they conduct studies on developing several types of SDDS theory, including nanoparticles and

biosensors that are integrated with AI. The basis on which start-ups will be selected is based on their level of development, the interaction that they have with SDDS and their readiness to be included in interviews.

The data was obtained by conducting interviews, which focused on founders and other stakeholders of the identified start-ups. The interviews were in-depth and semi-structured. The interviews dealt with uncovering the problem that these start-ups had with commercialising their technologies and the methods that they had utilised in order to alleviate this problem. The collection of secondary data included also publicly available business plans, reports, regulatory filings, and financial statements as well as market analyses.

The Business Model Canvas and TRL mapping were to be employed to investigate the business strategies and technological preparedness of every start-up. The framework combines these tools so that the start-ups can get a complete picture of how they can evaluate the business model and technology readiness in relation to a successful commercialisation.

3. RESULTS

Thematic Analysis

Theme 1: Regulatory Challenges

One of the major themes that were common in all the interviews is the burden of approval processes in the regulation. Entrepreneurs are presented with a complicated and usually ambiguous regulatory process, especially in innovative technologies like SDDS, where new formulations of drug delivery are involved. One respondent stated,

"*Finding our way through the FDA approval process has been one of the most time-wasting parts of our development. We sent our nanoparticle based drug delivery system, but the procedure to be followed was not well defined. Are you reality checking, like each review process is also a brand new experience*" (Participant A, Start-up 1).

Another respondent highlighted,

"*What we have is the absence of clear regulations to smart devices. The regulatory framework was not mindful of technologies such as ours and this resulted in dysfunctionally long delays in spite of the fact that our preclinical data were very good*" (Participant B, Start-up 2).

This is because these responses have depicted the confusion and ambiguity caused by the regulatory bodies on innovative start-ups in the bioscience sector. Since the SDDS field has new concepts, in most cases, regulatory frameworks are not adapted to these advanced technologies, causing an obstacle to start-ups.

Theme 2: Funding and Financial Sustainability

Another prominent theme identified in the interviews was the challenge of securing sufficient funding to cover the high R&D costs associated with SDDS development. Start-ups often face financial constraints that limit their ability to proceed through the lengthy and expensive process of clinical trials and market readiness. One of the respondents said,

"*Our biggest issue is funding. Even after securing an initial round of investment, the costs of clinical trials quickly outstripped our budget. We have to look for additional venture capital and grants, but it's tough*" (Participant D, Start-up 4).

Another participant said,

"*R&D is the most expensive part of the process. Without proper funding, we wouldn't even have made it past the proof-of-concept phase. Our next round of funding will determine if we can proceed with clinical trials*" (Participant E, Start-up 5).

The issue of funding is multifaceted, encompassing not just the direct costs associated with R&D but also the challenges of securing investors who understand the high-risk, long-term nature of bioscience startups. Many investors are reluctant to fund companies working on innovative drug delivery technologies due to the long timelines and the uncertainty of regulatory approval.

Theme 3: Technology Maturity and Readiness

Start-ups also expressed challenges related to assessing and advancing their technology to meet the readiness levels required for clinical trials and commercial applications. One of the participants said,

"*One challenge we've faced is determining exactly when our technology is ready for clinical trials. With nanotechnology, there's always the fear that we could miss something critical in the technology before moving to human trials"* (Participant C, Start-up 3).

Another respondent stated**,**

"*We've been mapping our technology's readiness with TRL. However, achieving TRL 7, where we are ready to start human trials, has taken much longer than expected. Every step forward in tech development feels like a major leap*" (Participant D, Start-up 4).

One respondent also highlighted,

"While the technology is promising, the challenge has been proving its effectiveness and reliability. We still have gaps in data that we need to fill before it is ready for broader clinical applications" (Participant E, Start-up 5).

This theme highlights the importance of the TRL framework for evaluating the technological maturity of SDDS. While the technologies hold promise, achieving the necessary levels of readiness for clinical trials and market application is a slow and uncertain process, often due to the complexity and novelty of the technologies involved.

Theme 4: Partnerships and Collaborations

Strategic partnerships and collaborations were another common theme that came out of the data. Several start-ups noted that the establishment of connections with other big pharmaceutical companies, contract manufacturers, and academic institutions was essential to the elimination of the barrier to commercialisation. One respondent said,

"Partnerships have played an essential part in our case. It could not have developed without the partnership with a big pharmaceutical company who helped it carry out a production scale-up process" (Participant B, Start-up 2).

Another respondent stated,

"We are in the process of identification of collab with universities in research. The work on science has been beneficial so that I could have an access to facilities and funds to bring our work to the next stage" (Participant A, Start-up 1).

Successful start-ups in the process of commercialisation were able to find their way through strategic partnerships that furnished them with the resources, experience, and credibility that were needed to grow their technologies to marketable levels. The establishment of partnerships with universities enabled start-ups to obtain the latest research, and the cooperation with manufactures and medicine companies became required to raise the production rate.

Theme 5: Business Model Innovation

The theme of business model innovation came up when the start-ups talked about the different methods they employed in modifying the business model to fit the needs of the healthcare market. It is flexibility and adaptability in business model design that contributed to success. One participant stated,

"*Our business model has had to change along the way. At first, we were only working on product development, but after this presentation, we have also understood that we should take into consideration how we are going to position and price our product in the marketplace*" (Participant C, Start-up 3).

Another participant stated,

"*It is the move away towards a pure R&D towards taking a view of customer segments, revenue models, and partnerships that has been very key in our development. We are turning our heads toward models that we can scale up and increase our reach*" (Participant D, Start-up 4).

In this theme, the importance of constant business model innovation is emphasised. Start-ups who effectively made it through the commercialisation process were those who were able to modify their strategy with the input that was given by investors, regulatory agencies and the market. They also had a dynamic business model that enabled them to adapt to the emerging situation in healthcare and technology.

Development of the Business Model Innovation Framework

The findings and implications drawn out of the thematic analysis of the interviews conducted with five bioscience start-ups have been used to create a comprehensive Business Model Innovation Framework that is applicable in the commercialisation of Smart Drug Delivery Systems (SDDS). The elements of this framework combine the most important issues and approaches defined in the interviews with the existing theory of business models. Market readiness, technology readiness, business model design, and strategic partnerships have been combined to give a comprehensive framework towards commercialisation. The specific barriers to the development of start-ups in the SDDS area identified in the course of the research and reflected in the literature are taken into account in the focused design of each component.[4,5]

Framework Components

Market Readiness Assessment

Market Readiness Assessment is the initial major part of the framework. The thematic analysis underlined that a cutting-edge issue that SDDS start-ups have to grapple with is how to learn about the demand in the market and its rivalry. Successful star-ups that carried on with successful commercialisation stressed the importance of considering the healthcare market carefully along with noting point customer areas in which they could bring value by using their technology. This element of the framework will enable start-ups to determine the demand of their SDDS technologies in specific therapeutic areas and establish the value propositions, which key into those segments. This knowledge is consistent with the literature that indeed market readiness tests should become essential conducts of a start-up to determine whether or not their products address current healthcare demands.[4] Additionally, a vital component of the Business Model Canvas is gaining awareness of the customer segments to help companies target the proper audience without losing the value to other clients and develop the appropriate value propositions.

TRL Mapping

The second part of the framework, technology readiness level (TRL) mapping, was featured as the tool that is essential to check the maturity of SDDS technologies. In this study, the start-ups highlighted the need to ascertain the right time that their technology is fit to move to the next level, whether in clinical trials or in the market place. The component assists start-ups in applying the TRL program to the evaluation of the existing state of their technology and the time when to turn to the regulatory authorities and increase production. These results complement similar ones by the study[7], who proposes to use TRL mapping as a productive method of measuring the potential of an emerging technology to be commercialised. Through the maturity level of their technologies the start-ups will be able to determine that they are ready enough to face the regulatory gaze and not repeat the costly errors of the clinical trials or expansion of the production.

Business Model Design

Its Business Model Design element focuses on the adaptability and agility that the strategy of bioscience start-ups must possess. On the basis of interviews, it is found that successful start-ups are those that have changed their business models depending on the response in the market and the emerging technological ability. This element promotes start-ups to adopt the Business Model Canvas[16] to speculate their value propositions, uncover customer types, debate on revenue designs, and develop significant alliances. The Business Model Canvas offers systematic manner to come up with a sustainable and scalable business model. Such perceptions are consistent with the Business Model Canvas standard that searches to create an understanding of why iterations of business models to evolve according to the requests and aspects of the market are important. It is aforementioned through the study[17] that flexible business model allows the start-ups to remain dynamic and adaptable to the fluctuating market trends, which is a major strength in the rapidly advancing bioscience facility.

Strategic Partnerships

The fourth and last element of the framework (Strategic Partnerships) was also found to be a key success factor in breaking down the commercialisation barriers. The interview information indicated the bioscience start-ups who were successful in scaling their SDDS technologies was able to achieve this through strategic partnerships with

pharmaceutical organizations, research universities, and contract research companies and manufacturing organizations. Such partnerships enabled them to find their way through regulatory processes of the time, financial resources and expand industry output. The necessity of cross-sector collaborations has been reflected in literature.[18]
It is through strategic partnerships that the start-ups will be able to acquire the resources, expertise, and manufacturing capabilities that they would not have been able to develop internally. This aspect underscores the importance of start-ups in trying to find such valuable partnerships so that they can be able to address the different commercialisation issues.

Framework Application in Start-ups

Practically, the Business Model Innovation Framework gives a guide to start-ups to evaluate and adjust their business models and technologies based on their response to the activities of commercialisation, within which they encounter problems. The framework takes you through the whole process of commercialisation right up to entering the market and this is in the initial research and development as well. The interviewed start-ups of this research gave sample on how it implemented aspects of this framework to effectively manage the intrigues of SDDS commercialisation. An example of such a start-up is in the oncology sector where a small company utilised the Market Readiness Assessment to help identify an area in need of the targeted cancer therapy. They designed their nanoparticles delivery system to suit this requirement, resulting in the description of a better value creation and investor interest. They also creatively utilized TRL mapping so that their technology is ready to undergo clinical trials and then approach the regulatory agencies. Also, their ability to form strategic alliances with bigger pharmaceutical firms helped them increase their production capacity which made them appealing to both investors and vascular care providers. A start-up that developed a product to help control diabetes chose this approach as well, as the Business Model Design helped to move the company beyond a purely scientific but narrow-minded approach and involved not only market and customer focus but some strategies of revenue. Their business model was flexible enough to reflect changes such as the introduction of flexible pricing and specific marketing of their technology to ensure that their technology was more accepted among the masses. The framework enables start-ups to determine the extent at which they are ready at every developmental stage, be it the technology and market preparedness, adaptation of the business model and development of partnerships. However, by adopting this measure, start-ups will understand the relevant barriers before it is too late to overcome them, and thus, implement strategies that will help them transition the developed products into the commercial world easier.

4. Discussion

The results of this research build useful knowledge in recognition of some of the major issues and approaches in commercialisation of Smart Drug Delivery Systems (SDDS) by bioscience start-ups. This research encompasses a critical discussion of barriers faced by five emerging firms in a thematic interview, through which it forms a critical view of some such barriers and how start-ups are overcoming them. The knowledge has played a pivotal role in coming up with the Business Model Innovation Framework, which considers market readiness, technology readiness and the designs well as business model design and strategic partnerships.
One of the most striking themes in this work was the regulatory uncertainty that start-ups in the SDDS industry had to deal with. One of the obstacles to the commercialisation of SDDS technologies identified was linked to regulatory challenges, as observed in the literature.[5] The responses during the interview highlighted this paucity of standardised directives in the novel systems such as SDDS, especially when it comes to nanotechnology and implantable microchips. This aligns with the arguments by the study,[4] who claim that emerging technologies are taking an undue long time to get approved in the market because there are no specific pathways of regulations.
The high cost of carrying out research and development especially clinical trials was identified as another major barrier in this study. This aligns with the report by the study[5] stating that on average the process of bringing a new biomedical product to the market costs more than 2 billion dollars with a significant part of the expenditures going to clinical trials and technology development. Start-ups are most of the time constrained to raise enough funding to finance these activities. This is reflected in the responses to the interview as without access to specialised venture capital biosciences start-ups can have a very difficult time meeting the cost of clinical trials that is the most costly step in the process of drug development.
To overcome this challenge, start-ups have used a range of mechanisms such as government grants, venture capital, and strategic transactions involving the other established pharmaceutical firms. Some of the start-ups also considered other sources of funding like crowdfunding or public-private partnerships so that the financial pressure can be alleviated. These strategies are also justified by the fact that the literature states that start-ups practically need external funds in order to expand their operations and advance them to the actual next level, during clinical trials stage.[4]
Separation of the value chain between the producers and the retailers was also another great obstacle to SDDS commercialisation. The start-ups usually have a challenge of forming a partnership with manufacturers, distributors, and regulatory bodies. Such fragmentation makes activities inefficient and slow when it comes to scaling up the production and delivering products to the market. The interviews also showed that start-ups which commercialised their SDDS technologies, managed to do so by establishing strategic alliances with other established companies in the pharmaceutical and manufacturing world. Such partnerships alleviated the predicaments that come with ramping up production since the likelihood of successful commercialisation increased.
The necessity of strategic partnerships was also stated in the literature as the collaborations with pharmaceutical companies, contract manufacturers, and research institutions were mentioned essential in scaling the production and passing by the regulatory barriers.[19]

Through cross-sector partnerships, start-ups can get access to priority assets, knowledge, and investments, which are very vital in the process of solving the challenges relating to commercialisation.

An innovation in business models would become another theme that will be essential in this research. The results indicated that successful companies that ensconced a changeable and evolving business model were the start-ups that were able to perform commercialisation of SDDS technologies. Start-ups were in a position to change their business models according to market responses and variable customer demands. This aligns with the study[20], who opine that business model innovation is the way to go to introduce sustainable value propositions, particularly within the volatile fields such as biosciences.

It was revealed that a useful tool to design business models capable of responding to change in market conditions and adjust customer needs is Business Model Canvas. With the help of customer segments, revenue streams, and value propositions, start-ups became able to cut their business models to remain successful further along. Also, those who mapped their technologies based on Technology Readiness Level (TRL) could manage to match their plans of business with the stages of their technologies, which meant that their efforts of commercialising technologies became timely and efficient.

The broad framework that this study has come up with is to combine these major themes; namely; market readiness, technology readiness, business model design and strategic partnerships that can be followed as a logic to be commercially ready. The framework is informed by the results of the thematic analysis so that the complexities involved in SDDS commercialisation can be unpacked by start-ups, and offer them a roadmap in this process. Market readiness assessment enables start-ups to determine the market needs and requirement and thus they are able to ensure their technologies are addressing the requirements found in the market. The technology readiness level mapping can assist the start-ups by allowing them to gauge their technological maturity level so that they can start the production process at the right level and involve the regulatory agencies. Business model design means that start-ups will have a sustainable and flexible strategy that can accommodate changes in the market. Lastly, strategic collaborations allow start-ups to deal with challenges related to production and distribution to scale-up their technologies successfully.

The formulation of this framework directly draws on the conclusions drawn by this study, which developed the barriers and business strategies that prove to have the greatest effect on commercialising the SDDS technologies. The qualitative data collected through interviews is complemented by theory and frames of reference on technology readiness and established theories of business models to help create a useful tool in the hands of bioscience start-ups in the SDDS domain.

5. CONCLUSION

This paper has set out to comprehend the commercialisation issues encountered by bioscience start-ups that are focusing on Smart Drug Delivery Systems (SDDS), and then develop an all-inclusive Business Model Innovation Framework to assist the start-ups with the commercialisation process. The study found the following main barriers, such as regulatory uncertainty, expensive research and development, and value chains splintering, and found out how start-ups overcome these obstacles.

The conclusions of this study reveal that engaging with the regulators early, having flexible business plans and establishing strategic pairings are valuable in breaking the commercialisation paradigm in the SDDS sector. The framework will help start-ups effectively organise the process of bringing their SDDS technologies to the market because a successful commercialisation of any technology is its alignment with the needs and demands of the market which is achieved through a multi-faceted approach to technology development presented by the framework developed based on combining the Business Model Canvas[21] and the Technology Readiness Level (TRL) mapping.[7]

The proposed research can be helpful in improving the currently available literature on the topic of the bioscience entrepreneurship framework by extending it to cover the areas peculiar to SDDS start-ups. In future studies, it is worth assessing how this framework could be used in other areas of biotechnology or what its role is as far as successful commercialisation of new technology in healthcare is concerned. Besides, more research is warranted on how regulatory agencies can create more standard and understandable regulations on SDDS technologies so that they can find faster entry into the market.

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