



Research Article

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Towards Integrated Bio Design-Related and Translational Platforms to Determine Co-Development for Adaptation of Innovative Biotechnologies and to Predict and to Prognosticate the Future of the Healthcare and Life Science Bioindustry

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Abstract

We are used to consider innovations in the life sciences and healthcare services as being discovery- and design-driven ones. And across worldwide basic, translational, clinical, and applied re-search, and throughout the bioindustries, scientific breakthroughs have been the launching point for principal bioproduct developments in the translational trajectory. Even the most innovative healthcare technologies being translated in the right direction, would provide patient benefits only when adopted by clinicians and/or patients in actual practice. So, co-development between innovation-related builders and customers is a key agile principle. And in the coming wave of innovation in the broad-scope applications, learning rapidly what new bioproduct features work well for clinicians and patients will become even more crucial.

Accelerating innovation to improve quality is a key policy target for healthcare systems around the world. And policies that aim to support this process should seek to control the wider conditions that nurture peer-to-peer influence. The advanced design-based translational research into interpersonal influence in health settings may improve implementation of change initiatives. So, promoting innovation within national health systems has been set as a key target for health care professionals and policy makers in the civilized world and has led to the establishment of several innovation pathways to encourage the invention, development and implementation of cost-effective technologies that improve health care delivery. These pathways operate at different stages of the innovation pipeline, with their scope and work defined by location, technology area or bioindustry sector, based on the specific problem identified when they were set up.

Due to the worldwide experience and practice say, the efficiency and efficacy of the national economy are determined and dictated by the innovative trends, generated by fresh knowledge and their transfer into the scientific, industrial, and social areas to maintain the national stability and extensive development of the country. So, we would have to have the life sciences deeper understood to be re-shaping tomorrow's healthcare whilst doing it today!



Introduction

The goal of making the healthcare sector more efficient and effective in all stages of innovation (invention, development, and implementation) is a primary concern for health companies and governments around the world. In the last several decades, life sciences per se have changed monumentally than virtually any other field of science or engineering. Until recently, the objective of most basic research was to generate new knowledge and advance understanding of biological and biochemical processes. The steady, incremental advance of the life sciences has now started yielding important benefits of healthcare, particularly through the pharmaceutical and nutraceutical bioindustry focusing on new healthcare interventions and delivering innovation and greatly enhanced nutritional and agricultural production and productivity through improved process innovation and new technology. Discoveries from the basic research undertaken in publicly/private funded research institutions are now being applied more rapidly and broadly for societal impact.

World over bioindustries have forayed into wide-ranging applications in medicine, agriculture and food, informatics, nano-

and forensics, among others. However, moving forward there would be advances that are yet to be imagined. Industries will adopt new technologies and there will be new discoveries made that will impact every aspect of our lives-from health to food production, climate, and environment. Therefore, to create favorable conditions for sustainable development and deployment of biotechnologies to act as an engine for the knowledge-based bioeconomy, it is imperative to have a strategy rooted in the upgraded perspective to drive biotechnology to the next level.

Over the past decade, a focus on needs-based innovation has emerged as an alternate strategy for biomedical and healthcare product development, particularly in the domain of biomedical technology (medical devices and diagnostics). Influenced by the spread of design thinking across campuses and corporations alike, innovators are beginning to focus on developing a deep understanding of clinical and healthcare needs. So, the World would strongly need a new strategy in getting the upgrading healthcare services re-armed soon! In this way and through the strategy mentioned, the integration of Clinician Interaction Platforms, Bio design, Bioengineering & Translational Applications, Advanced Biomanufacturing platforms, Bioindustry & Bioeconomy (Figure 1).



Figure 1: The basic components of the updated strategy for bringing high-tech products to the market.

The basic components of the updated strategy for bringing high-tech products to the market. could be recognized as a sunrise sector that needed focused attention. The cornerstone of the strategy was to focus on building coherence and connectivity between disciplines and bring together variegated skills across sectors to enhance synergy. Boundaries between disciplines once considered distant are now beginning to blur and because of their convergence given birth to newer opportunities and challenges to get the trend and thus the strategy moved forward whilst building a skilled workforce to accord top priority in the renewed mission of the modern scientific community.

In the era of Personalized and Precision Medicine (PPM), digital technologies, drug discovery and development face unprecedented opportunities for product and business model innovation, fundamentally changing the traditional approach of how drugs are discovered, developed, and marketed [1]. Critical to this transformation is the adoption of new technologies in the drug development process, catalyzing the transition from serendipity-driven to data-driven medicine. This paradigm shift comes with a need for both translation and precision, leading to a modern Translational Medicine (TraMed) approach to Drug Discovery, Diagnostic Biotech, Personalized Neurobiology and Precision Food omics, and development [2].

This tremendous revolution aimed to unveil the global secrecy of the Hi Tech has come in the late 20th and then continued in the 21st century, with smart cross- and transdisciplinary technologies and PPM has witnessed interdisciplinary technology innovations in healthcare with a continuous growth in life expectancy across the globe.

As PPM becomes a greater focus in healthcare, biotechnology, biomanufacturing and bioindustry continues to play a big role in its future. PPM holds tremendous potential to remake the healthcare industry. By applying a deeper understanding of diseases with richer patient data and advanced analytics and then modeling the pathologies, PPM can help physicians tailor medicines and nutraceuticals to the needs of individual patients, rather than by broader populations, leading to better outcomes at potentially lower costs [1-4].

As current challenges to emerging biotech and PPM fall away, new ones may rise in their place. But the bioindustry recognizes that PPM promises a brighter future in terms of patient outcomes, PPM will transform the entire Biopharma and Biotech value chain, from early development to companies' go-to-market models, and the next years will be a crucial window for the companies to capitalize on this promise. They need to take risks and more actively engage with stakeholders throughout the healthcare ecosystem.

Life science companies are making unprecedented strides in PPM to optimize medical treatment. Also, biotech companies are

developing new OMICS-tests based on the premise that patients' personal health and molecular data will help physicians optimize their treatments [3,4]. For instance, Roche is becoming a leader in research-focused healthcare with combined strengths in pharma, biotech, and diagnostics with truly differentiated medicines in a variety of healthcare subareas. Roche's personalized healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients.

There are valid reasons for the bioindustry's interest: PPM holds the potential to change the way medicine, including along with pharmacy, neurobiology and food omics is practiced. This is leading to greater pressure on pharmaceutical and nutraceutical companies to create bioproducts that deliver markedly, measurably better (including with preventive and prophylactic efficacy) care, with greater value (Figure 2). Biotechnology deals with the application of biological knowledge and techniques pertaining to molecular, cellular and genetic processes to develop significantly improved products and services. Biotechnology products and processes have ensured ease of living, improved health care, agriculture output and created livelihood opportunities, etc [5].

Meanwhile, engineering biology and Bio design present a suite of opportunities to solve the problems people and the planet face, now and tomorrow. As well as bringing cheaper, greener, and custom-designed products to market, engineering biology can dramatically transform the processes that underpin existing industries, such as helping to lessen the impacts fossil fuels have while they are still an embedded component of our lives [6]. Engineering biology and Bio design are addressed along with stakeholders and policymakers, to practitioners, encouraging greater collaboration between different disciplines and industries that can achieve vastly more together, building on the precedent set by the private Biomanufacturing and government's Bioeconomy strategy. Greater communication and collaboration, and a heightened focus on real-world applications, combined with more sophisticated and intelligent marketing will drive progress in engineering biology.

Moreover, engineering biology is the application of rigorous engineering principles to the design of biological systems (BIODESIGN), with the objective of contributing to economic activity and sustainable and resource-efficient solutions to the societal challenges faced in food, chemicals, materials, water, energy, health, and environmental protection. "Bio design" today is a big tent where everyone who self-identifies as a bio designer can hang out. Bio designers are edging toward a new set of design practices and ideas that are as plausible and exciting as they are inchoate. Today we can feel out the shape and texture of today's Bio design community to get a hazy but exciting view of the future. More precisely, bio designers see the potential of biotechnology and its ability to shape the living world [7].

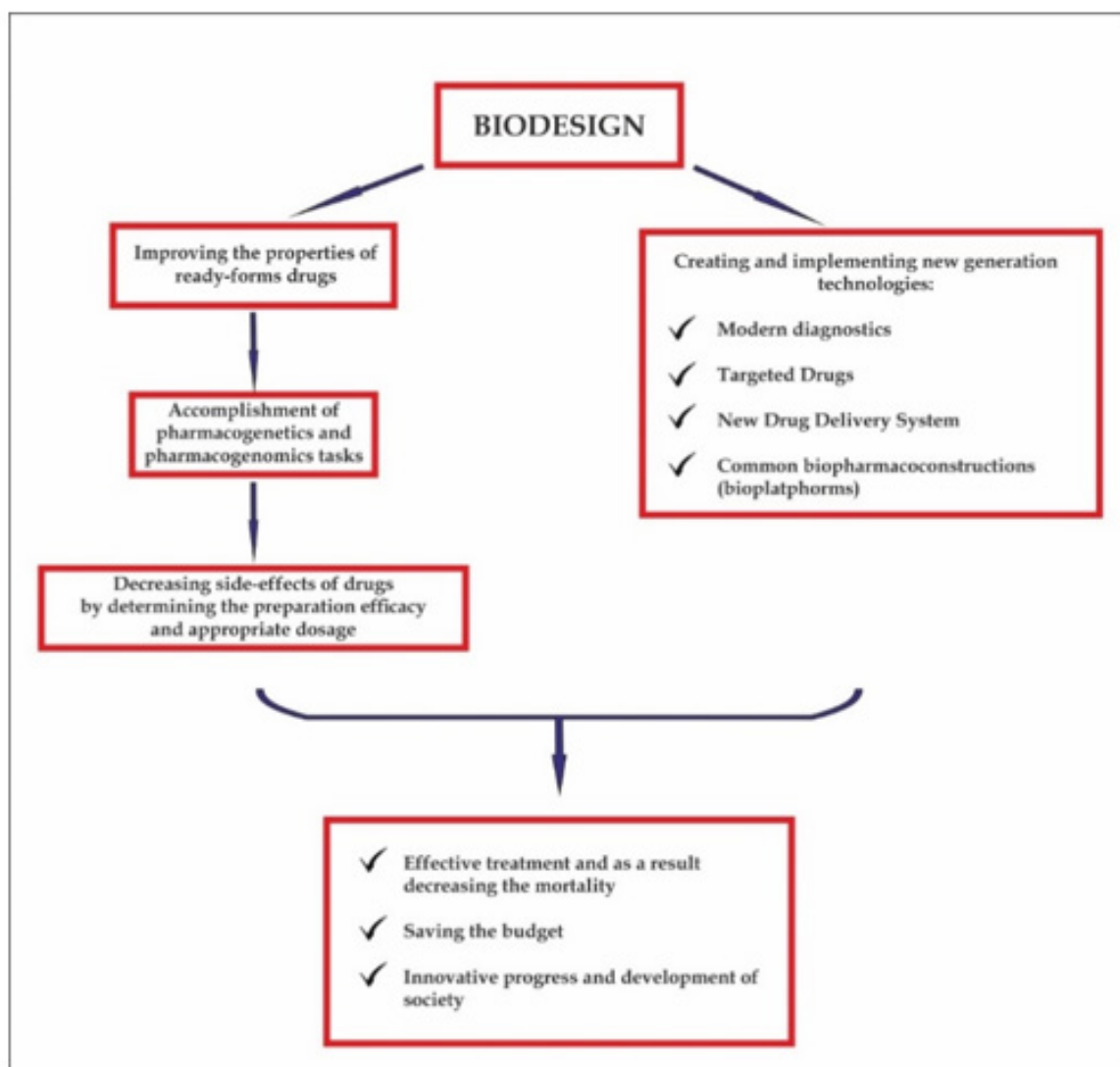


Figure 2: The art of creating and modifying bioproducts of the next generation.

A new Bio design practice emerged as a hybrid of bio art and speculative design incorporated, which incorporated lab activities and living materials and often critiqued contemporary biotechnology by exploring alternative applications and futures. As Bio design becomes a professional practice, this foundation will prove enormously important as innovators balance consumer and industry demands, ethics, and implications, and scientific feasibility.

Today, a handful of professionals in the biotech industry work in design. They are mainly generalists who have worked in both the biology lab and the design studio, and whose multitudinous roles include marketing and communications, experience and process design, product testing, art direction, partnership strategy, and more. In the rare case, bio designers in leading roles have transformed entire bioproduct pipelines. As this underlying platform technology becomes increasingly embedded, and the core design-build-test-

analyse cycle becomes increasingly automated, so scientists can concentrate more on end uses - shifting the focus towards what we term 'Bio design'. The shifts in Biotech in focus towards 'Bio design' is already becoming a reality for simpler systems, whilst remaining a significant future target for more complex systems. And the rapid progress has focused attention on the increasing importance of digital biology and laboratory automation in unleashing a new business sector of Bio design.

A further challenge is the ability to control intra- and intercellular functions through the deployment of smart, designed, biological information and control systems. This will be enabled by the development of effective, robust Bio design tools that will make the high-level design and implementation of systems and synthetic biology solutions more accessible to a wide range of users. Following the above-mentioned, bio design and biotechnology now

encompass a wide range of fields such as biochemistry, genetics, and molecular biology. Every year, new technologies and products are developed in fields such as medical, agriculture, and industrial biotechnology. So, bio design & Biotechnology innovations require extensive infrastructure, such as omics platforms, bio foundries, computer-aided bio design, Biomanufacturing and bio marketing and large-scale growth facilities. Such resources are difficult for private companies – let alone innovative startups – to create and operate on their own means. And partnerships and strategic alliances can provide the backbone of a biotech ecosystem ready to uptake new ideas and initiatives, test them, generate prototypes,

and license them to the commercialization partner. Such targeted partnerships can facilitate such applications by providing critical infrastructure, bio design R&D expertise, and a way for companies to access and implement transformative technologies without shouldering an unreasonable amount of risk [8].

Industry Dynamics

The global biotechnology market was estimated at USD 793.87 billion in 2021 and is expected to be worth around USD 1,683.52 billion by 2030, poised to grow at a noteworthy CAGR of 8.7% from 2022 to 2030 (Figure 3).

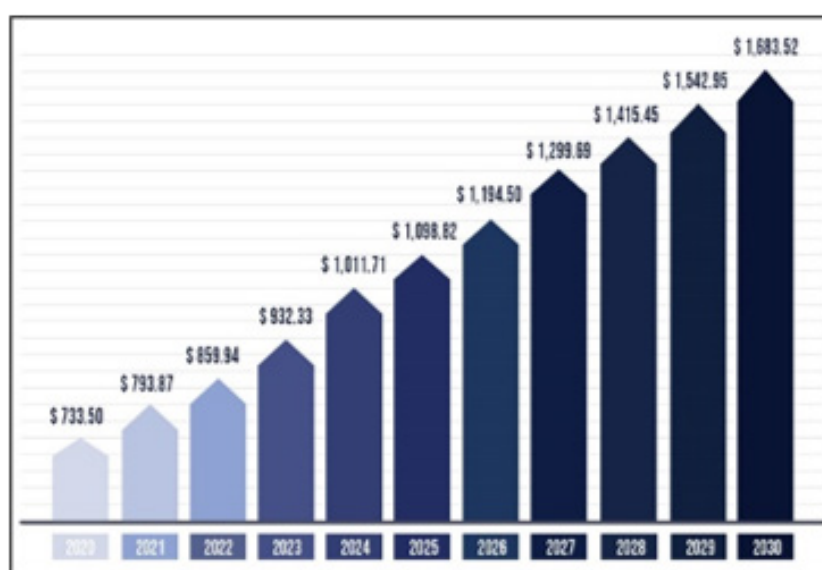


Figure 3: Expected explosive growth of biotechnological products on the market from 2020 to 2030.

Biotechnology is becoming more important since large amounts of data generated by techniques such as nucleic acid and protein acid sequencing require data interpretation and management for medical and future research objectives. Consequently, the biotechnology market is likely to be driven by increased demand over the forecast period. And, as we might see, the key market players are concentrating their efforts on bringing healthcare-related, nutraceutical and agricultural innovations to market to boost production through long-term solutions. Growth Drivers Increasing awareness regarding the broad application of biotechnologies, such as human and animal nutrition, environmental protection, drug development, along with agricultural improvements are expected to drive the biotechnology market growth over the forecast period. Based on the application, the bio pharmacy dominates the biotechnology market during the fore-cast period. The increasing prevalence of diseases is mostly responsible for the growth of the segment. Thus, the rising demand for medicines and drugs is driving the growth of bio-pharmacy segment in the biotechnology

market [9].

On the other hand, the bioinformatics is expected to grow at rapid pace of 21.5% during the forecast period. The rising demand for nucleic acid and protein sequencing, rising initiatives from private and government organizations, propelling the growth of proteomics and genomics, and rising research on molecular biology and drug discovery are all growth factors for the bio-informatics segment. The bio-informatics segment is predicted to increase rapidly during the forecast period because of aforementioned factors.

Insight by Technology

The tissue engineering and regeneration segment holds a strong share of the market in 2021 and is expected to grow considerably over the forecast period due to its advantages of regenerating patients' tissue and organ and the advancement in technology. Furthermore, the rise in the operational regenerative treatments due to increasing cases of obesity and diabetes among

the population is expected to boost industry growth over the forecast period.

Nowadays the health care industry is more focused on improving the quality of medical treatments by developing minimally invasive techniques for diagnosis and including with the help of new advances in the field of nanotechnology. Nanotechnology through nanorobotics offers enormous advantages over the conventional methods for diagnosis and treatment, precisely because of the knowledge gained from converging domains like molecular biology, mesoscopic/supramolecular chemistry, and mesoscopic physics at the nanometer scale. Regardless of some limitations, nanorobots are fascinating nanodevices for the implementation of advanced biomedical instrumentation. Reliable applications for nanorobotics in medicine include early diagnosis and targeted drug delivery for cancer, arteriosclerosis, tis-sue engineering, pharmacokinetics monitoring of drug delivery, cellular assistance in inflammatory responses, ophthalmology, and many others.

Nanobiotechnology segment is expected to grow at a significant pace over the forecast period due to increasing novel drug discovery along with rising investment by several private and government organizations. In addition, nanotechnology offers new potentials

for life-saving medical and cancer treatment.

Insight by Application

Biopharma segment is expected to grow significantly over the forecast period. Increasing prevalence of chronic diseases among the population has led several private and public businesses to introduce novel drugs and vaccines for the treatment, which in turn has benefitted the segment growth [10].

The global biotechnology market integrating bio design, bioengineering and Biomanufacturing, is driven by favorable government initiatives owing to the growth of the biotechnology sector. Government initiatives are oriented towards modernizing the drug regulatory pathway, standardizing clinical studies, improving reimbursement policies, and speeding up the product approval process, thereby offering lucrative growth opportunities to the market. Experts from bioindustry, academia and not-for-profit organizations presented their vision for the future of the field and provided guidance to funding and regulatory bodies to ensure that PPM, bio design and Biotech TRIO research is carried out responsibly and can realize its full potential since the TRIO offers innovative approaches for engineering new biological systems or redesigning existing ones for useful purposes (Figure 4).

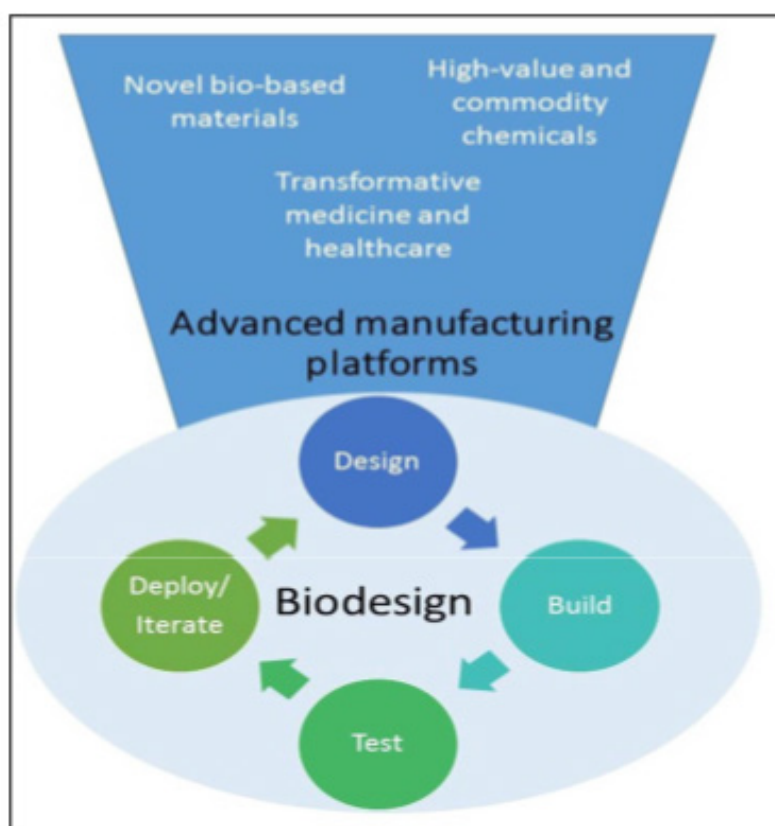


Figure 4: PPM, bio design and Biotech TRIO.

PPM, bio design and Biotech TRIO is developing into a bio design platform where it will be possible to apply the “design-build-test-iterate (or deploy)” to predictably create cells or organisms able to produce a wide variety of novel molecules, materials or even cells for multiple applications. It has been described as a disruptive technology at the heart of the bioeconomy, capable of delivering new solutions to global healthcare, agriculture, manufacturing, and environmental challenges [11].

Capacity for innovation and technology development in biotechnology rests largely on access to core facilities and instrumentation of the next step generation in an upgraded proportions mentioned above. To enhance R&D opportunities in basic, disciplinary, and trans-disciplinary sciences, we would provide sustained support predominantly to basic sciences, including:

- a) multi-disciplinary research in biology to be encouraged; attract non-biologists to address bio-logical questions.
- b) individual excellence to be complemented with mission and team-driven approaches to trans-form basic findings into applications.
- c) encourage emerging technologies in the rational and upgraded proportions and functional configuration.

For instance, basic research initiatives are important for the understanding and treatment of chronic diseases, whilst understanding pathogenesis, virulence factors, patterns of transmission, host susceptibility and development of new technologies and countermeasures for disease detection, diagnosis and treatment would be important.

- a) Environmental (exposal) factors that facilitate emergence, maintenance, and transmission of infections: Studies on impact of environmental changes and climatic variability on the emergence of microbes.
- b) Evolution of pathogenic infectious agents that result in changes in their infectivity, virulence, transmissibility, and adaptations at molecular level.
- c) Host and pathogen factors that facilitate emergence and spread of infections including the use of antimicrobial and immune-suppression drugs.

Translational Focus to Include

Host-targeted interventions as therapeutics specific for infectious diseases: to stimulate innovation in the discovery and development of therapeutics that target host-encoded functions required for infection, replication, spread and/or pathogenesis. Host and pathogen biomarkers for rapid diagnosis.

a) Development of assays for high-throughput screening for use in probe and pre-therapeutic discovery. This would also ensure indigenous production of quality laboratory reagents.

b) Development of new diagnostic tools that can support rapid and accurate diagnosis including field conditions especially for disease of national concern in immunocompromised subjects.

Meanwhile, it's becoming more evident that a large portion of the public is skeptical about science and medicine. In fact, the public's fears over what's in their food and medication, what businesses are doing with our health data, and what scientists are capable of, are changing business practices in ways that are detrimental to public health, the economy, and the discipline of science overall.

Bio Design & Bioengineering

bio design & Bioengineering-to apply the knowledge of allied quantitative sciences such as physics, mathematics, chemistry, computer sciences and engineering in the domain of biological sciences for effectively addressing the biomedical challenges. In this sense, bio design, Biotech and Biomanufacturing TRIO being Trio, is an example of a dual-use technology: it promises numerous beneficial applications, but it can also cause harm humans or damage the environment. For example, there is huge value in our ability to engineer viruses to be more effective and specific shuttles for gene therapies of devastating inherited disorders; however, engineering viruses may also lead to the creation of even more deadly pathogens by those intent on harm.

Exchange of ideas and information is vital in promoting and sustaining research and development. It helps in innovation and in finding newer solutions to long battled challenges. The collaboration to be included would also include private players for attaining competitive advantage. Yet, to this point, the biomedical incumbents have remained unthreatened in the delivery of healthcare; while there have been interesting partnerships, acquisitions, and enabling technology development, there have been no at-scale examples of healthcare disruption by a major tech player to date. An important open question is whether one set of players will ultimately win the day, or whether the coming years will see greater collaboration and joint product development that will ultimately transform how most patients interact with the healthcare system.

Many major biotechnological research problems are best addressed with a multidisciplinary approach that bridges life sciences and physical sciences. Bioengineering integrates principles from diverse technical and biomedical fields, and the resulting multi-disciplinary research provides new understanding, novel bio products and bio tools, and innovative technologies that improve basic knowledge, human health, and quality of life. In this

sense, bio design is a tool of R&D for unlocking the interdisciplinary barriers and translating rules of nature for solving complex societal challenges. The major solutions could be translated as high value-added products when bio design intersects with entrepreneurship which is described generally as the capacity and willingness to develop, organize, and manage a business venture to create a societal added value, along with any of its risks to make a profit. It entails recognizing the right opportunity, finding resources to pursue the opportunity, and creating the right team of bio designers to do so.

Entrepreneurship based on innovation has immense growth potential. Design-driven innovation gains importance in modern translational approaches because solutions must be innovative enough to solve the high challenging bioengineering problems. Design-driven innovation and bioengineering as a discipline have commons in their descriptions; design-driven strategy has a multifurcating approach consisting of strategy formulation by listening; ideation strategy by interpretation, strategy implementation by broadcasting like the multidisciplinary bio design-related approaches.

Most policymakers and academics agree that entrepreneurship is critical to the development and wellbeing of society. Entrepreneurs drive and shape innovation, thereby speeding up structural changes in the economy. Entrepreneurship is thus a catalyst for economic growth and national competitiveness. Startups in bio design usually have a revolutionary idea however design driven innovation approaches should be used; to develop innovative business models that are scalable and profitable as well as to develop innovative bio marketing strategies. A startup should not be focused on the product only; market, competitors, users, suppliers to be identified real opportunities for innovation.

The new-age business ventures are more idea-centric and not just product-based. The key to success in business is not just inheritance; it is creation of more wealth and the constant innovation, from the prevailing to the next best practices. An entrepreneur, typically, is inspired to start a business because the entrepreneur perceives a consumer need that is not being adequately filled.

Meanwhile. The Bio-entrepreneurship can be described as a process of action an entrepreneur undertakes to establish his bio design- and bioindustry-related enterprise being based on a set of the transdisciplinary principles to have the final bioproduct developed and succeeded. Bio-entrepreneurship is the attitude of mind to seek opportunities, take calculated risks and derive benefits by setting up a bioindustry-related venture.

In the context of bio design and biotechnology, the bio-entrepreneur operates in a knowledge-based and science-based bioindustry, where competitive advantage is achieved through the effective management of intellectual property emanating from good life science. The bioentrepreneur is often a scientist/researcher-turned-entrepreneur who wishes to see their research successes put into practice through commercialization.

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