Why is it so challenging to achieve unicorn status in medical innovations?

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A unicorn is a solution characterized by rapid growth dynamics that achieves significant reach and capitalization of one billion dollars in a short time – is a rare asset, with companies attaining such a status considered an unnatural exception to the rule. Nevertheless, unicorns serve as invaluable sources of inspiration for subsequent teams developing new technologies. In the era of digitalization of medicine, miniaturization, popularization of biosensors, and virtually universal access to the internet, the number of ideas to improve medical care is skyrocketing[1]. The growing healthcare needs of patients, coupled with the disproportionately limited capabilities of traditional medical care, ensure that interest in medical innovations remains at the center of attention[1]. However, what must happen for a medical innovation to be suitable for rapid implementation? What problem must it solve to be scalable at an international level? What features must it possess to be adopted by all participants in the medical care system? Undoubtedly, there are more questions than answers, making the debate on finding a unicorn in the world of medical innovations particularly interesting.

A unique feature of a medical unicorn is its ability to address the needs of the three main stakeholders in the healthcare system – the doctor, the patient, and the payer. Often, a unique technology assists in achieving this goal by providing greater value than currently applied solutions (existing standard). These may include new digital solutions, drugs, or medical devices, and their medical value is assessed based on clinical efficacy, safety, and cost to the healthcare system[2].

Undoubtedly, a challenge faced by anyone wanting to operate in this area of innovation is meeting the specific requirements of the medical market. Above all, it is heavily regulated, and medical data are subject to special protection[1]. Consequently, clinical safety and patient privacy must be prioritized, as evidenced by compliance with applicable regulations and obtaining medical certification. When discussing the commercial success of solutions financed from public funds, demonstrating cost-effectiveness is crucial, as is positive verification by the Agency for Health Technology Assessment and Tariff System (AOTMiT) in the case of the Polish market[3].

To achieve a unicorn status, a key goal is not only to prove clinical value and commercialization potential but also to ensure that the product is unique enough to solve a significant problem on a large scale. It must address needs on a global scale, as is the case with new diabetes drugs[3]. Simultaneously, a medical unicorn's muscles must be strong and flexible to adapt the business model

and operations to diverse markets. This challenge is particularly difficult for technology companies, as local regulations and healthcare organization methods vary depending on the country[4]. Therefore, to survive, a unicorn candidate must have charisma and flexibility ingrained in its DNA, set realistic goals, and plan. A fundamental characteristic of successful companies is exceptional determination and resilience in building clinical value[4].

One of the critical elements characterizing medical enterprises, particularly those striving for unicorn status, is the identification and resolution of unmet clinical needs. Before embarking on new solutions, needs must be carefully verified and adjusted to regulatory requirements[2]. An analysis of successful ventures indicates that a systematic approach to innovation in medicine is essential. One well-researched and verified methodology is the CIMIT model (Consortia for Improving Medicine with Innovation and Technology), which is based on an innovation cycle comprising five stages[3]. The first stage involves defining a frequent or urgent medical problem that requires a prompt solution. It represents the previously discussed clinical need, typically resulting from healthcare system inefficiency. The second stage involves designing the solution, creating a preliminary medical technology model based on the defined problem to address the identified clinical need. Presenting the solution at early stages and forging partnerships to attract relevant stakeholders is undoubtedly helpful at this point. The third stage involves rapid prototyping and testing, or the creation and verification of preliminary medical technology models. This stage is characterized by quick iterations, error detection and elimination, and continuous improvement of subsequent solution versions. The fourth stage involves testing the medical technology in real-world conditions, i.e. on patients and within a clinical environment. At this stage, the efficacy and safety of the new medical technology must be assessed. Robust clinical evidence must be gathered to confirm the product's clinical value, addressing the needs identified at the beginning of the process. The final, fifth stage of the CIMIT cycle is market implementation, i.e. introducing the new medical technology for widespread use[3].

Employing systematic methodologies for managing the medical innovation process increases the chances of success, reduces the risk of errors and product-market misalignment, and optimizes costs[4]. Simultaneously, it explicitly defines successive project stages, thereby clarifying the expected time and resources required for project implementation to stakeholders. The CIMIT methodology has proven helpful in creating various innovative medical solutions, such as new diagnostic methods, patient monitoring systems, medical robots, and advanced surgical tools[3]. Thanks to the CIMIT methodology, innovative solutions can quickly be introduced to the market, contributing to improved medical care and reduced healthcare costs. CIMIT demonstrates how collaboration between science, business, and medical personnel can foster the development of innovative medical solutions[3].

Despite the use of advanced project management methods, medical innovations are among the riskiest business ventures[4]. Therefore, assessing the financial risk of creating innovative medical solutions is crucial for business success. Among medical unicorn candidates, one can often find brilliant concepts that nonetheless require thorough analysis and consideration of multiple factors[4]. Those wishing to realize their dreams must acquaint themselves with the real costs of such an undertaking and anticipate potential profits and losses. Accurate financial risk assessment requires understanding the various factors influencing investment success. Not only business factors but also political and economic variables, such as inflation, interest rates, or the risk of armed conflict, must be considered[4]. An appropriate approach to financial planning requires a suitable time perspective and the consideration of all factors influencing the outcome[4].

There is a tendency towards excessive optimism regarding the success of these ideas, assuming they will function perfectly and generate revenue[4]. Hence, it is vital to consider the actual costs and

risks associated with these ideas, analyzing not only a balanced scenario but also a pessimistic one. We should be aware that in addition to internal project risks, the political and economic climate will also have an impact[4]. Long-term financial modelling and consideration of all potential variables related to revenue and costs during business concept creation are necessary. A realistic perspective on potential business success or failure should be maintained, and various options should be considered during the planning process before investing time and money in a business idea[4].

In conclusion, developing medical innovations is of paramount importance from a public interest perspective, as they provide solutions that improve societal health, optimize healthcare expenditure, and offer a competitive edge to medical entities[1]. A medical unicorn should deliver clinical value, safety, and cost-effectiveness while addressing significant global problems and simultaneously having a flexible business model that adapts to diverse markets and regulations[2]. Building medical unicorns is a high-risk endeavor requiring substantial investments with a long payback period[4]. Nevertheless, considering the invaluable goal of patient health, there are brave individuals who embark on this path[4].

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