Artificial Intelligence in Parkinson's Disease Detection: A Strategic Assessment for U.S. Market Entry

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ABSTRACT:

This study explores whether it would be feasible to introduce an Artificial Intelligence (AI)-based diagnostic tool for Parkinson's Disease (PD) to the United States (U.S.). The product is Saudi Arabian and is intended to reduce resource consumption by improving diagnostic accuracy and efficiency. The U.S. market offers a favorable environment because of its advanced healthcare infrastructure and stable democratic political structure. The analysis looks at the political and economic climate, including government support, market opportunities, regulatory compliance, and the strategic advantages of partnerships with local entities. The study suggests that the AI-based diagnostic tool could revolutionize PD prediction and management, offering significant benefits in terms of healthcare outcomes and cost efficiency. Also, it recommends a strategic entry through local partnerships and adherence to U.S. regulatory frameworks to ensure successful market penetration and long-term success.

Keywords: Parkinson's disease, neurological disorders, AI-based diagnostic tool, healthcare sustainability, healthcare infrastructure, noninvasive diagnostics, healthcare technology, innovation in healthcare, market penetration, healthcare outcomes, and healthcare outcomes.

1. Introduction

This study examines the political and economic climate in the U.S. analytically to determine whether it would be feasible to introduce a PD diagnostic medical product that utilizes AI—a product that significantly advances healthcare sustainability. The product reduces the total resource consumption typically involved in the diagnostic process by focusing on improving diagnostic accuracy and efficiency, which is in line with sustainability goals. The U.S. provides a favorable atmosphere for the implementation of cutting-edge healthcare technologies because of its stable democratic political structure. This study utilizes previous published research, which discussed an innovated technique to predict PD, and address how this context fits with the U.S. market entry as a new Saudi Arabian product meant to enhance patient care while lowering financial and environmental expenses (Hawi et al., 2022).

The U.S. market presents a promising opportunity for emerging medical technologies because of its advanced healthcare infrastructure and high per capita income. Also, it's known for its stable democratic administration and powerful economic structure,

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provides a fertile ground for the acceptance of novel healthcare solutions. The successful deployment to get a significant market share requires market penetration, which is defined as establishing a foothold in an already-existing market and successfully reaching target customers to increase market share, which needs the implementation of strategies that are specifically designed to reach and serve the target market within a given geographic area. Furthermore, strict adherence to laws such as the Foreign Corrupt Practices Act is required; these are essential for preserving market integrity and promoting an atmosphere free from corruption, both of which are critical for sustainable commercial operations. Moreover, Strategic collaborations with existing local entities are encouraged to facilitate market entry and to harness their expertise and resources efficiently.

Forming strategic partnerships with local U.S. entities can present significant challenges due to cultural differences, varying operational practices, and potential conflicts of interest. These factors may complicate collaboration efforts, delay project timelines, and impact overall effectiveness. To address these challenges, the following is important to consider:

- Cross-Cultural Training: Implement comprehensive training programs for the team and our partners to understand cultural nuances and improve cross-cultural communication. For example, training sessions on American business etiquette, negotiation styles, and decision-making processes.
- Clear Communication Channels: Establish regular meetings and use collaborative tools such as Slack or Microsoft Teams to facilitate transparent and ongoing communication. This includes setting up shared project management platforms like Trello or Asana.
- Conflict Resolution Mechanisms: Develop protocols for resolving disputes quickly and fairly, such as third-party mediation services or establishing a joint conflict resolution committee.
- Due Diligence: Conduct thorough research and assessments of potential partners to ensure alignment in operational practices, business ethics, and strategic goals. This includes site visits, interviews with key stakeholders, and reviewing past partnership performances.

Ultimately, this introduction underlines the potential of the AI-based diagnostic product to revolutionize the landscape of PD prediction through creative technology in the U.S. market as the upcoming sections will discuss it in detail. The authors support forming strategic partnerships with regional partners to take advantage of their infrastructure and market knowledge, which will allow for successful market navigation and long-term success in the U.S. healthcare industry.

2. Political Environment Analysis

A federal system characterizes the organizational form of the U.S. government with three branches: the executive, legislative, and judiciary. The division of powers protects decision-making mechanisms about medical device rules and policies. The adoption of the AI-based diagnostic tool could be accelerated by some government initiatives, such the FDA's Breakthrough Devices Program. Relying heavily on government initiatives like the FDA's Breakthrough Devices Program carries inherent risks if policies change or programs are discontinued. To mitigate these risks, the following is important to consider:

- Risk Assessment: Analyze the potential impacts of changes in government policies on our market entry strategy. For example, studying past instances where similar programs were altered or discontinued and their effects on other companies.
- Contingency Plans: Develop alternative pathways such as seeking approval through other expedited FDA programs like the De Novo pathway or utilizing the 510(k) premarket notification process if the Breakthrough Devices Program is unavailable.
- Private Funding: Identify and pursue private funding sources, including venture capital firms, healthcare-focused investment funds, and grants from non-governmental organizations.
- Advocacy Networks: Engage with industry groups and advocacy organizations such as the Medical Device Manufacturers Association (MDMA) to stay informed about policy changes and actively participate in lobbying efforts. Also, the supportive regulatory climate for medical developments is demonstrated by recent examples of successful healthcare innovations in the U.S., such as the swift approval of COVID-19 vaccinations.

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2.1 Political System and Structure

Political stability would facilitate the implementation of a noninvasive diagnostic apparatus that utilizes AI to diagnose PD based on recorded acoustic signals. The proposed Technology exhibits cost-effectiveness and mitigates the need for invasive operations (Mitchell, 2018).

2.2 Government Stability

Government support in the form of finance programs or incentives could facilitate the widespread adoption of this technology by healthcare institutions nationwide. The stable democratic administration in the U.S. facilitates the process of approving and regulating innovative medical devices.

2.3 Future Political Consideration

The U.S. faces the most significant political risk in the future due to potential alterations in healthcare policy, government regulation, and the allocation of funds for medical equipment such as the AI diagnostic tool for PD detection. The fate of this and comparable medical devices may hinge upon political deliberations on healthcare advancement, availability, and cost-effectiveness.

2.4 Bribery and Corruption Risk Index

To ensure compliance with U.S. legislation such as the Foreign Corrupt Practices Act, it is imperative to consider the bribery and corruption risk index before releasing the diagnostic tool. The U.S. has implemented anti-corruption laws and enforcement mechanisms, such as the Foreign Corrupt Practices Act (FCPA), to deter bribery and corruption (Agarwal & Kumar, 2022).

The position of a country in Transparency International's Corruption Perceptions Index is contingent upon the perceived level of corruption within its public sector. The U.S. typically exhibits a relatively low position on this index, indicating a comparatively lower prevalence of bribery and corruption than numerous other countries.

3. Economic and Business Environment Analysis

The United States spent \$4.1 trillion on healthcare in 2020, according to recent data, suggesting a healthy market for future medical innovations (Abernethy et al., n.d.). Here are some examples of how recent economic developments, such inflation and exchange rate fluctuations, have affected the healthcare industry. These examples shed light on possible obstacles facing the AI-based diagnostic tool.

3.1 Demographics and Population Dynamics

To sell the product well, the population's dynamics is important to be considered, growth rate, and distribution. Compared to rural areas or villages, metropolitan areas tend to have a better access to healthcare technology. Therefore, understanding age groups can help adjust marketing efforts to attract the proper target population. Focusing marketing efforts primarily on urban areas might result in the neglect of rural populations, which limits overall market reach. To ensure comprehensive market coverage, the following is important to consider:

- Rural Market Analysis: Include detailed demographic studies of rural areas to understand their healthcare needs and access challenges. For example, analyzing data from the National Rural Health Association (NRHA) on rural healthcare facilities and patient demographics
- Telemedicine Platforms: Leverage telemedicine platforms such as Teladoc or Amwell to reach rural populations. This includes partnerships with these platforms to offer our diagnostic tool as part of their service offerings.
- Local Healthcare Providers: Collaborate with rural healthcare providers and clinics to raise awareness and facilitate access. For instance, running pilot programs in rural hospitals to demonstrate the efficacy of the diagnostic tool.
- Targeted Communication: Tailor marketing messages to address the specific needs and concerns of rural populations, such as emphasizing the convenience and accessibility of non-invasive diagnostics.

The U.S. is home to more than 330 million individuals from all walks of life. Immigration and natural rise are the main drivers of the constant population growth rate (Dietz & Rosa, 1994).

• Population Distribution and Age Demographics: The age distribution is diverse, with a sizable part falling between the 25-54 age bracket. Major cities draw a

disproportionately significant population share, making urban areas denser than rural ones (Bloom et al., 2003).

3.2 Per Capita Earnings and Wealth Inequality

The high level of income per capita in the U.S. indicates a generally well-off populace. However, there are gaps in wealth distribution between regions and economic brackets. To study the changing structure of international commerce, Bureau of Economic Analysis (BEA) is creating data that will give a fuller and more complex picture of U.S. trade. Global value chains, including a rising number of nations producing a single good or service, will be easier to study with the new data.

3.3 Major Exports and Key Trading Partners

A strong healthcare sector is seen in the fact that the U.S. is a leading supplier of medicines and medical devices. Europe, Asia, and Canada are important trading partners for healthcare technologies. In the future, international cooperation and exports may be possible after the domestic launch of the AI-based diagnostic equipment.

Inequality in income is often linked to disparities in health. According to Lynch (2000), Various theoretical and practical issues arise when health disparities are viewed via a psychosocial lens, considering how individuals perceive their relative disadvantage and the psychological effects of inequality. Disparities in income are associated with a wide range of other socioeconomic factors, some of which have the potential to hurt people's health (Lynch et al., 2000).

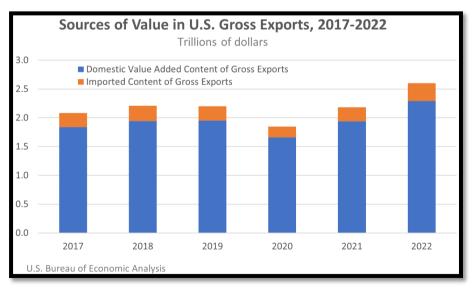


Figure-1: The value of U.S. exports in 2022 was \$308.6 billion, or 11.9%, according to newly revised trade in value added (TiVA) figures (Global Value Chains | U.S. Bureau of Economic Analysis (BEA), n.d.).

3.4 Business Environment and Regulatory Landscape

Regarding high-tech industries like healthcare, the U.S. government does its best to encourage foreign investment. Policies that fund research and development encourage companies to produce innovative technology. Simplified regulatory procedures and robust intellectual property protection contribute to a high level of ease of doing business. Market access and commercialization may be hindered by healthcare trade laws, such as FDA approvals (Golub, 2009).

Another study proposes the idea that MNC strategists consider the full life cycle—from entrance to operations in the country to exit—when deciding which nations to invest in. Additionally, businesses are prepared to forego either easier or more liberalized laws later in the life cycle for more rigorous regulations. Both host country policies and the strategies employed by multinational corporations in selecting which of the 189 countries to invest in can be informed by the findings (Contractor et al., 2020).

The device's successful launch depends on the U.S. business-friendly environment since simplified procedures speed up product development and commercialization. Maintaining conformity with rules regulating medical equipment and international trade agreements necessitates familiarity with trade regulations. The unique diagnostic technology stands a higher chance of acquiring market traction and providing significant healthcare solutions to persons at risk of PD if we consider these considerations within the context of the U.S. economic and political landscape.

3.5 Inflation Levels, Currency Exchange Rates, and Devaluation Risks

As a result of the Federal Reserve's efforts to keep prices stable, inflation in the U.S. is kept at a moderate level. Changes in the value of one currency relative to another affect production costs, pricing tactics, profitability, and competitiveness in the market. Considering variables such as manufacturing localization, exchange rates, and quantity-based shipping pricing, this paper investigates how these variables affect the performance of multinational enterprises. It then develops a unified optimization model to minimize significant costs (Fahimnia et al., 2013).

The complexities and financial risks associated with currency exchange rate fluctuations and inflation are significant and can impact production costs, pricing strategies, and overall profitability. To manage these risks, the following is important to consider:

- Hedging Strategies: Use financial instruments like forward contracts or options to hedge against currency exchange rate fluctuations. For example, locking in exchange rates for a specified period to stabilize costs.
- Financial Risk Assessments: Conduct regular assessments to evaluate the impact of inflation and exchange rate changes on our financial projections. This includes scenario analysis and stress testing to understand potential impacts on profitability.
- Flexible Pricing Models: Develop dynamic pricing strategies that can adjust based on economic conditions. For instance, incorporating clauses in contracts that allow for price adjustments based on inflation indices.

• Inflation Monitoring: Keep track of inflation trends using tools and reports from financial institutions like the Federal Reserve and incorporate this data into the financial planning.

To further reduce financial risks, evaluating the dangers connected with the possibility of the U.S. dollar's depreciation relative to other currencies is necessary. Exchange rates for the U.S. dollar, a prominent worldwide currency, can rise and fall in response to news about the economy and international politics. An increase in AD is likely to occur with a devaluation since AD = C+I+G+X-M, a decrease in imports and an increase in exports both result from a reduction in the price of exports.

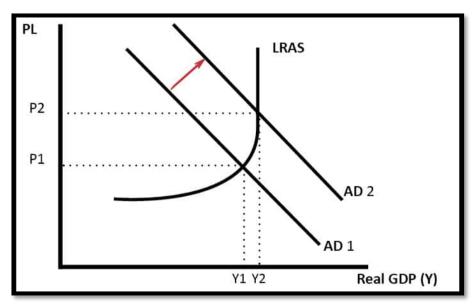


Figure-2: Inflation will result from increasing AD if the economy is nearing full capacity. An increase in AD causes inflation (Pettinger, 2018).

Market mood and macroeconomic factors determine the likelihood of a depreciation relative to the dollar.

3.6 Education, Literacy Levels, and Labor Market Dynamics

A highly educated workforce and high literacy rate are hallmarks of the U.S. robust educational system. Industries and regions have a more significant impact on labor expenses than others; for example, specific sectors and cities pay more than others. The availability of educated and literate Americans is crucial for the diagnostic gadget to be developed and maintained by a professional workforce. Furthermore, production expenses, which in turn impact pricing tactics, are heavily influenced by labor costs.

3.7 Participation in Free Trade Agreements and Regional Economies

The U.S. participates in some regional trade blocs and agreements, such as the World Trade Organization, NAFTA (now USMCA), and bilateral trade accords. In addition, being a part of regional economic and trading blocs can open doors to other

markets and easier commerce, which can make the device more accessible and affordable both at home and abroad.

3.8 Legal System: Rights and Contract Enforcement

Legal protections for IPR and contract enforcement are vital in the United States. Courts and regulatory bodies back the enforcement of laws about intellectual property and contracts. Protecting the intellectual property rights linked to AI-based diagnostic Technology requires careful consideration of the legal framework. To encourage innovation and boost R&D spending, robust systems must be in place to safeguard intellectual property and enforce contracts. Stakeholders may strategically traverse barriers and capitalize on chances to bring new diagnostic equipment into the U.S. healthcare industry by thoroughly studying these economic and business environment aspects.

4. Cultural Dimensions of Doing Business in the Country

The effective introduction of telehealth services into the U.S. market, for instance, highlights how crucial it is to comprehend communication methods and cultural preferences. Cultural variations, such the need for individualism, should be considered in marketing tactics since they might affect consumer behavior and decision-making.

4.1 Major Religions, Ethnic Makeup, and Languages

The country's main religions may impact doing business and interacting with others. Recognizing religious sensitivity in different cultures is essential. Marketing and communication tactics may need to adapt to the country's linguistic and ethnic diversity.

4.2 Extracurricular Activities and Sports

One way to increase brand engagement and connect with locals is to include popular sports and leisure activities in the marketing initiatives.

4.3 Variations in Family Roles, Norms, Views, and Practices

Differences in views, values, traditions, and behaviors can impact consumer preferences, purchasing decisions, and commercial relationships. Everyone involved in making decisions and conducting business should respect the importance of family.

4.4 Distinct Business Practices

Some cultures place a premium on being on time and getting things done quickly, while others place a higher value on getting people to agree on something and establish relationships. The key to fruitful business encounters is mastering the local customs around the meeting, negotiating, relationships, attire, status, and gift-giving (Marketing & Weissburg, 2022).

4.5 Unique Aspects of Written, Oral, and Nonverbal Communications

There can be many non-verbal, verbal, and written communication methods. Cultural subtleties in expressions, gestures, and language usage must be considered. To avoid misconceptions and miscommunication, developing communication tactics specific to the local audience is essential.

4.6 Describing the Country's Culture Using Hofstede's Cultural Dimensions Model

Business hierarchies and decision-making processes can be impacted by power distance, which refers to hierarchical systems and respect for authority. Individualism and collectivism can influence marketing messaging and team dynamics, which allude to preferences for group cohesion above individual achievements.

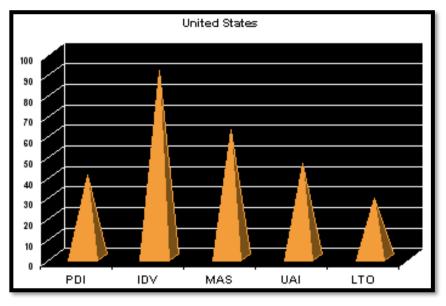


Figure-3: The U.S's high Individualism (IDV) grade reflects a culture with less social ties. People are more self-reliant and care for themselves and their families (U.S. - U.S. or American Geert Hofstede Cultural Dimensions Explained, n.d.).

U.S. received the Long-Term Orientation (LTO) Dimension. At 29, the U.S. LTO is the lowest Dimension compared to 45 globally. Low-LTO societies prioritize culture and duty. The U.S. scores 40 on Power Distance (PDI), below the global average of 55. This indicates a more egalitarian society in government, organizations, and families. By encouraging cooperation amongst power holders, this perspective stabilizes culture.

5. Market Opportunity Analysis

In 2022, out of all seven million countries, the U.S. had the most considerable PD market size, valued at approximately USD 3.2 billion (Parkinson's Disease Market Report 2032: Epidemiology, Therapies, Clinical Trials, Companies, n.d.). Experts predict that it will have grown by 2032, as Illustrated in Figure-4 below. As the population ages and more individuals become aware of PD, the number of Americans diagnosed with the condition has been on the rise. Several traditional diagnostic tools are available, but there

aren't many AI-powered options that are especially designed to diagnose PD using voice signals, according to a thorough competitor analysis. The success of AI-based diagnostic systems like IBM Watson in the treatment of cancer demonstrates the potential for such technologies in other fields, including PD (As IBM Moves Forward, Study Finds Promise in Watson Health Decision-Making, n.d.).

While the rising incidence of neurological illnesses suggests a promising market, it does not guarantee success. The product will face competition from established diagnostic tools and other emerging innovations. To gain a competitive advantage, the following is important to consider:

- Competitive Analysis: Conduct detailed studies comparing our AI-based diagnostic tool with existing products. For example, creating a comparison matrix that highlights key features, pricing, accuracy, and ease of use.
- Unique Benefits: Emphasize the unique advantages of our diagnostic tool, such as its non-invasive nature, higher accuracy in early detection, and cost savings. Also, provide case studies and pilot results that demonstrate these benefits.
- Clear Value Proposition: Develop marketing materials that clearly articulate the value proposition. For instance, brochures, whitepapers, and video testimonials from early adopters in pilot programs.
- Marketing Investment: Allocate resources to marketing campaigns that highlight the innovative features. This includes online advertising, presence at medical conferences, and partnerships with influential healthcare organizations.

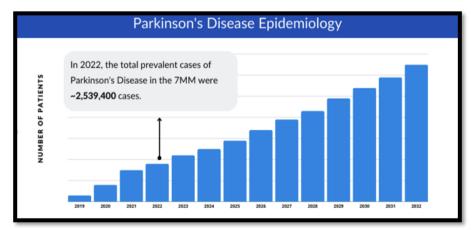


Figure-4: Parkinson disease market insight report (Parkinson's Disease Market Size, Share | Parkinson's Disease Companies, n.d.).

5.1 Product Potential in the U.S. Market

The rising incidence of neurological illnesses, such as PD, among the elderly population in the U.S. bodes well for the future of this product's market. New diagnostic tools are in high demand due to the increasing public interest in PD and its early detection and treatment alternatives. New treatments for PD, such as gene therapy, stem cell therapy, and disease-modifying therapy, have emerged because of increased public awareness of the disease and continued research. There are a lot of potential atypical Parkinsonian syndromes that can share symptoms with PD, making a correct diagnosis difficult. These syndromes include Multiple System Atrophy (MSA), Corticobasal Degeneration (CBD), Dementia with Lewy Bodies (DLB), Progressive Supranuclear Palsy (PSP), and others. Additionally, the diagnostic process is slowed down due to the absence of reliable measurement tools and devices (Espay et al., 2016).

5.2 Current Usage of AI Diagnostic Tools

Unfortunately, no noninvasive alternatives exist to invasive imaging testing, clinical evaluations, and symptom monitoring for diagnosing PD AI based diagnostics are finding an audience in a market eager for better, more accessible, and cheaper diagnostic tools.

5.3 Competitive Products in the U.S. Market

Although there may be more conventional ways to diagnose PD, an absence of AI powered diagnostic tools aims squarely at detecting PD in audio signals. There might be rivals in the market for neurological disease diagnostic tools or healthcare Information Technology (IT) solutions powered by AI (Gerke et al., 2020).

5.4 Distribution Networks for Medical Devices

Healthcare providers, suppliers of medical equipment, online medical platforms, and specialty healthcare merchants are all examples of distribution channels that may be utilized. Through partnerships with healthcare networks, hospitals, and clinics, it is possible to facilitate product distribution and access to targeted customers.

5.4 Prominent Advertising Methods in the U.S.

Digital platforms, medical journals, conferences, healthcare websites, and targeted online commercials are all examples of advertising media channels utilized to promote healthcare items in the United States. Increasing product awareness and reach can be accomplished through social media, healthcare influencers, and partnerships with healthcare organizations.

5.5 Total Market Size and Potential for AI diagnostics

The high prevalence of PD and the emphasis placed on enhancing healthcare outcomes have contributed to the large market for PD diagnostics and related technologies in the United States. The prospective market for diagnostic equipment based on AI is contingent upon some factors, including adoption rates, reimbursement policies, regulatory approvals, and the competitive environment.

5.6 Target Consumers and Demographics Analysis

The target market consists of healthcare practitioners, neurologists, hospitals, clinics, research organizations, and people who are experiencing symptoms of PD or who are at risk for developing the disease. Individuals who suffer from neurological disorders, populations that are becoming older, and medical professionals who specialize in neurology are all examples of demographic information. According to recent demographic

projections, there will be 94.7 million people in the United States who are 65 years of age or older by 2060, which highlights the expanding market for PD diagnostics (Vespa et al., n.d.). Strategic alliances with medical associations and focused advertising in medical journals have shown to be effective marketing approaches for connecting with healthcare professionals.

6. Market Entry Mode

Strategic reasoning and joint ventures are good ways to enter the U.S. healthcare market since they provide the advantages of pooled resources and local market expertise. Case studies of new product introductions in the healthcare market, including robotic surgery system, offer important insights on how to get over regulatory and market obstacles.

6.1 Suitable Market Entry Mode

• Reasoning: this approach offers swiftly access new markets, eliminate regulatory barriers, and adjust to local preferences and rules by partnering with a local entity. Furthermore, it facilitates the dissemination of knowledge and technology, broadening the market and boosting the competitiveness of enterprises.

6.2 Case Studies of Market Entry Strategies: Successes and Failures6.2.1 Pfizer's COVID-19 Vaccine

Pfizer, a multinational pharmaceutical company, entered the American market with its COVID-19 vaccination by BioNTech helps. The company and the U.S. government deliberately collaborated to expedite vaccine development, production, and delivery as part of operation warp speed. By leveraging its current infrastructure, experience in vaccine development, and regulatory knowledge, Pfizer launched its vaccine on the American market and obtained an Emergency Use Authorization (EUA). The seamless introduction of Pfizer's COVID-19 vaccine into the market demonstrated the company's capacity to collaborate closely with law enforcement, respond promptly to public health issues, and carefully abide by regulations (Chiplunkar et al., 2022).

6.2.2 Theranos' Blood-Testing Device

Theranos, a healthcare technology firm, failed to enter the market despite early excitement and investment because of regulatory non-compliance, a lack of validation for its technology, and a decline in stakeholder confidence. The business ran into problems with quality control, regulations, and allegations of deceptive behavior with their blood-testing technology (Williams, 2022). The healthcare industry places great importance on adherence to rules, transparency, and product validation, as demonstrated by Theranos' unsuccessful market entry approach.

The world looks to the U.S. as a multicultural and diverse country with a democratic framework regarding advancements in science, technology, and healthcare. Among the challenges it faces are issues with market accessibility and distribution, intricate healthcare systems, intense rivalry, and stringent regulatory compliance. The nation's communication styles, which emphasize open, sincere, and succinct interactions, reflect its

meritocratic, innovative, and individualistic principles. The U.S. offers a huge market opportunity for AI-powered medical devices due to its vast population, advanced healthcare system, and wealth of research resources. The industry can advance due to several factors, including growing consumer demand for innovative treatments, advancements in AI and healthcare IT, and supportive regulatory measures for medical innovation. Challenges include the competition for treatments on the market, legal restrictions, reimbursement guidelines, and market entry strategies. To fully realize the potential of AI-based PD treatments, one must adhere to regulations, have innovative ideas, engage in strategic planning, and possess in-depth understanding of American politics, economics, culture, and the market.

6. Conclusion

In conclusion, the political climate in the U.S. offers a favorable backdrop for the introduction of the AI-based PD diagnosis tool because of its stable democratic administration and government backing for medical developments. It is crucial to manage any changes that can affect the product's success and market introduction, such as changes in government regulations, financial allocation, and healthcare policy. For market entry and expansion, it is also essential to comprehend the business and economic environment, including distribution routes, market size, demography, and regulatory frameworks.

Effective marketing and communication strategies require an understanding of the diversity of religions, races, languages, and business practices. Understanding the nation's cultural norms and preferences can be gained by utilizing Hofstede's concept of cultural dimensions. An examination of market opportunities indicates that the U.S. market for PD diagnostics is expanding due to an older population and rising neurological condition awareness. The AI-based diagnostic tool has the potential to successfully enter the U.S. market and provide important long-term healthcare solutions to people at risk of PD with a targeted market entry strategy, such as licensing with a local partner and learning from the successful and failed market entry strategies of other multinationals and reasoning.

A potential limitation of the study is the resource-intensive nature of continuously monitoring and adapting to changes in U.S. healthcare policies and regulations. This ongoing effort may strain the company's resources and divert focus from core business activities. To manage this, the following is important to consider:

- Dedicated Teams: Establish dedicated regulatory affairs teams tasked with monitoring policy changes and ensuring compliance. This team will use tools like Regulatory Intelligence platforms to stay updated.
- Efficient Monitoring Mechanisms: Implement software solutions such as Veeva Systems or MasterControl to streamline the tracking of regulatory updates and compliance requirements.
- Strategic Planning: Integrate regulatory monitoring into the strategic planning process to balance it with core business activities. This includes setting clear priorities and resource allocation strategies.

• Automation Tools: Explore the use of AI and machine learning tools to automate parts of the monitoring process, reducing manual effort and increasing efficiency. To further increase its market potential, future study should examine the possibility of modifying the diagnostic tool for application in additional neurological illnesses.

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