**AI CONSULTANCY REPORT**

Company Name: Nordic Health Insights

Country: Finland

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Customer manager: Petri Laaksonen

Consultation Type: Regular

**AI Maturity Level**

Nordic Health Insights is a digital health technology company that has been operating for four years, specializing in personalized wellness solutions for chronic disease management. The company focuses on developing AI-powered mobile applications that help patients with diabetes, hypertension, and cardiovascular conditions monitor their health metrics and receive personalized recommendations. The company has successfully launched two mobile applications serving approximately 15,000 active users across Nordic countries and has established partnerships with several Finnish healthcare providers. They have implemented basic machine learning algorithms for health trend analysis and are developing an advanced predictive system for health deterioration alerts. Based on their operational AI systems and growing technical capabilities, the company's AI maturity is rated as **moderate**.

**Current Solution Development Stage**

The company has developed and deployed two successful mobile health applications that use basic AI algorithms to track user health metrics and provide personalized insights. They are currently working on an advanced AI system that can predict potential health complications by analyzing patterns in user-generated health data, including blood glucose levels, blood pressure readings, physical activity, and dietary information. The primary focus is now on developing a comprehensive risk assessment model that can provide early warnings for health deterioration events, such as diabetic complications or cardiovascular incidents. This advanced system is in the prototype development stage, with clinical validation studies being planned in collaboration with Helsinki University Hospital. The company is working with medical professionals and data scientists to ensure clinical accuracy and regulatory compliance. The objective is to create a certified medical device that can integrate with Finland's healthcare system and provide actionable health predictions to both patients and healthcare providers.

**Validity of Concept and Authenticity of Problem Addressed**

The concept addresses the significant challenge of managing chronic diseases, which affects over 2.5 million Finns and represents a major burden on the healthcare system. The approach of using continuous health monitoring combined with AI-powered risk prediction is highly relevant, particularly given Finland's aging population and increasing prevalence of lifestyle-related diseases. The idea is grounded in established medical research and addresses a genuine need for proactive healthcare management. However, the solution must navigate complex regulatory requirements for medical devices and ensure clinical validation to gain acceptance from healthcare professionals and patients.

**Integration and Importance of AI in the Idea**

AI is the cornerstone of the proposed solution, serving as the primary technology for analyzing complex health data patterns, identifying risk factors, and generating personalized health predictions. The system's ability to provide early warnings and personalized recommendations depends entirely on the accuracy and reliability of AI algorithms. The integration extends beyond simple data analysis to include natural language processing for patient communication and machine learning models for continuous improvement based on clinical outcomes.

**Identified Target Market and Customer Segments**

The primary target market consists of individuals with chronic health conditions, particularly diabetes (Type 1 and Type 2), hypertension, and cardiovascular disease patients in Finland and other Nordic countries. Secondary markets include healthcare providers seeking digital health tools, corporate wellness programs, and health insurance companies interested in preventive care solutions. There is significant potential to expand to elderly care facilities and home healthcare services. The market is well-validated through existing user base and partnerships with Finnish healthcare institutions, with clear expansion opportunities as the population ages and digital health adoption increases.

**Data Requirement Assessment**

The company collects and analyzes diverse health data including continuous glucose monitoring readings, blood pressure measurements, heart rate variability, physical activity data from wearables, dietary logs, medication adherence records, and subjective wellness scores. The system also incorporates demographic data, medical history, and lifestyle factors. Current data collection covers basic health metrics, but the advanced AI system requires higher-frequency data collection and integration with medical devices certified for clinical use. Data quality standards must meet medical device regulations, and the system needs to handle missing data common in patient-generated health data.

User engagement varies significantly, with active users providing multiple daily measurements while others contribute data irregularly. Seasonal variations in activity levels and health behaviors present additional challenges for consistent data collection and model training.

**Data Collection Strategy**

Current data collection utilizes mobile applications with manual user input and integration with consumer health devices (smartwatches, glucose monitors, blood pressure cuffs). The company maintains a secure, GDPR-compliant cloud infrastructure with end-to-end encryption for health data. Integration with electronic health records (EHRs) is planned through partnerships with Finnish healthcare providers. Patient consent management and data governance frameworks are established, but clinical-grade data validation processes need enhancement. Real-time data synchronization from medical devices is being implemented to improve data accuracy and timeliness.

To enhance clinical utility, it is recommended to establish direct integrations with certified medical devices and implement automated data quality assessment algorithms. Additionally, developing standardized clinical protocols for data collection and creating secure data sharing mechanisms with healthcare providers will improve the system's medical value.

**Technical Expertise and Capability**

The company has a multidisciplinary team including software engineers, data scientists, clinical specialists, and regulatory affairs experts. Internal capabilities cover mobile app development, basic machine learning, and health data management. However, advanced AI expertise in medical applications, clinical validation methodology, and regulatory compliance for medical devices require external collaboration. The team has experience with Finnish healthcare regulations and GDPR compliance, providing a strong foundation for medical AI development.

**Expectations from Fair Services:**

The company expects guidance on regulatory pathways for AI-based medical devices in Finland and EU, technical recommendations for clinical AI validation methodologies, and support in connecting with potential clinical research partners. They are interested in accessing funding opportunities for digital health innovation, particularly through Business Finland and EU health technology programs, and require ongoing technical advisory support for clinical AI development and regulatory approval processes.

**Recommendations**

* Establish a clear regulatory compliance strategy aligned with EU Medical Device Regulation (MDR) requirements for AI-based medical devices. Engage with Finnish Medicines Agency (Fimea) early in the development process to understand approval pathways.
* Implement robust clinical validation protocols that demonstrate both technical performance and clinical utility. Design randomized controlled trials in collaboration with Finnish healthcare institutions to validate AI predictions against clinical outcomes.
* Develop comprehensive data governance frameworks that address patient privacy, data security, and ethical use of health data. Ensure compliance with both GDPR and healthcare-specific data protection requirements.
* Create interoperability standards that enable seamless integration with Finnish healthcare IT systems, including electronic health records and national health data platforms like Kanta services.
* Address the challenge of data quality and missing values through advanced imputation techniques and uncertainty quantification methods specifically designed for medical AI applications.
* Establish clinical advisory boards with Finnish healthcare professionals to guide AI development and ensure clinical relevance. Include patients and patient advocacy groups in the development process.
* Develop a technical roadmap that balances innovation with regulatory requirements, including milestones for clinical validation, regulatory submissions, and market approval timelines.
* Investigate collaboration opportunities with Finnish research institutions, including University of Helsinki, Aalto University, and VTT Technical Research Centre, to leverage academic expertise in medical AI.
* Plan for scalability and integration with Finland's national health information systems, considering both technical and organizational requirements for healthcare system adoption.
* Schedule regular advisory sessions to review clinical validation results, discuss regulatory compliance challenges, and support preparation of funding applications for Business Finland's health technology programs and EU Horizon Europe health initiatives.

**AI Maturity Levels:**

**Low:** Companies that are in the early stages of AI integration or development and/or typically in the ideation phase and/or with only a proof of concept. They have limited data, resources, and expertise, and a minimal understanding of AI. AI is minimally or not at all used in workflows, with no data management processes or AI roadmap in place.

**Moderate:** Companies that are progressing in their AI journey, moving beyond the proof of concept stage with functional solutions. They have adequate data, resources, expertise, and understanding of AI. AI is either fully or partially integrated into their workflows, supported by established or developing data management processes, and guided by a partially or fully formulated AI roadmap.

**High:** Companies that have already developed advanced AI products and have an established customer base. AI is fully or partially integrated into their workflows, supported by established data management processes, and guided by an AI roadmap. They require assistance with specific technical details or when developing new AI applications on top of their existing solutions.