Sink or Swim: Connected Health Software
Grasping the Innovation Opportunities by Mitigating Risk

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Abstract: Connected Health innovation can be an opportunity for companies to develop and grow, if they take opportunity to develop solutions for healthcare. In this paper, we discuss a case study where a very small company in Ireland developed a connected health solution, but in doing this, discovered a number of risks which they faced. Working with a research from the University of Limerick (author 1), they developed mitigation strategies to avoid these risks, and subsequently developed an updated version of their initial connected health solution. This software, Global-MN, has been implemented by a charity in India, Varanasi Children's Hospital. We present information about both the initial and updated product, illustrating how overcoming the risks has resulted in the company redesigning their product for a global market. Data entered via this software is now providing Varanasi Children's Hospital with information and analysis, which, in turn, is allowing them to provide a better service and improve the nourishment of children in India.

1 INTRODUCTION

The term "Connected Health" describes a new form of healthcare service that depends on technology innovation to deliver healthcare. This is defined by Richardson (2015) as:

Connected Health is where patient-centred care results from process-driven health care delivery undertaken by healthcare professionals, patients and/or carers who are supported by the use of technology (software and/or hardware).

The development and implementation of connected health solutions cannot be undertaken by technologists alone – it must be carried out hand-in-hand with patients and healthcare professionals (HCP). For any connected health solution to work efficiently and effectively, the processes through which they work must also be developed. Therefore, while connected health products include software, e-health (electronic health) and m-health (mobile health), connected health must be recognised as a much wider concept.

Furthermore, for companies to move into the Connected Health market, they need to develop their products with healthcare in mind. Many innovative ideas have been proposed. With the global older population growing dramatically, and the costs of healthcare rising, connected health is an innovative marketing opportunity. To support this growth, the first author is on a Science Foundation Ireland (SFI) Industry Fellowship, where she has worked for the past 2 years (part-time) to carry out research within ADA-Security. She has developed insights into how connected health innovations should be structured so that both the healthcare consumer and the company can benefit. In this research (Richardson et al., 2016a), we are also interested in understanding how companies make the transition from one product to the next. Through the case study presented in this paper, we have been enabled to investigate how a very small company can shift extensively to a different product line through mitigating risk. This paper discusses these mitigations which ensure that the company could complete product development. Our research question is:

What mitigations should a very small enterprise implement to ensure success in the growing Connected Health market place?

The remainder of this paper discusses how the innovation process works for very small enterprises, presents a case study, outlines the company products, presents the research method used and

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discusses the risks faced and mitigations implemented.

2 BACKGROUND

In Ireland, small-to-medium sized enterprises (SMEs) account for 97% of all enterprises and the most important contributors to the economy (Forfás, 2007). The need for SMEs to become more innovative has probably never been greater given the new economies, new technologies, and hyper competition with which they are challenged (Drejer, 2002). Rogers (2004) regards innovation "*as a key ingredient in business success*".

Foster (1986) advocated that the diffusion of innovation over time follows an S-Curve (Figure 1). Under the S-Curve paradigm, firms go through various stages in the diffusion of innovation (Silveria, 2001), namely start-up, scale, maturation (compete) and decline (transition). Small to medium sized enterprises (SMEs) experience different market challenges at each stage ranging from survival and market validation, transitioning to challenges in increasing market share, and entering and expanding into the new markets.

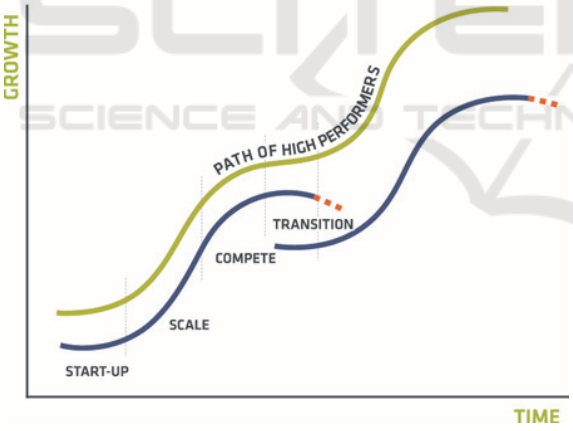

Figure 1: Double S-Curve Model (Squarespace, 2016).

SMEs need to recognise how to operate in markets with constraints, e.g. regulatory challenges, so as to retain their competitive advantage as they climb the S-Curve. Coupled with the diffusion of innovation is market adaptation, with particular attention being given to the stage and the focus of the market at each stage of the S-Curve. Credence must be given to the market forces at play given the very strong influence they may assert on the success of innovations in new targeted markets (Bolton and Thompson, 2013).

3 RESEARCH PROJECT

In her role as an SFI Fellow, the first author of this paper has spent 2 years part-time as a participant observer within ADA-Security, a very small enterprise in rural Ireland. Working closely with the managing directors (authors 3 and 4), she studied their connected health software development and innovation processes. She carried out interviews, attended meetings, discussed strategy, analysed the existing product, Local-Health and was involved in the development of their new product Global-MN.

4 CASE STUDY

ADA-Security is a company, whose focus has been on installing security systems within homes and companies nationally. It is a very small enterprise located in rural Ireland, over 50 miles from the nearest city. The local area has intermittent access to broadband, which is not uncommon in rural Ireland [Irish Farmers' Association, 2015].

The directors noted an opening in the market for the installation of home care systems, such as panic buttons and home monitoring. Innovatively, company has developed a number of services through which people can feel more secure and cared for in their homes. For example, they have developed activity monitors which can detect inactivity – if an older person has not risen by a certain time during the morning, and alarm can be activated. Their service also includes a friendly-call system which would have someone ring the older person during the day, reducing their feeling of social isolation. They now provide a combination of security, social and healthcare requirements.

Maintaining the security business and expanding into home care systems have ensured that the company has continued to be successful for over 2 decades. Examining the S-Curve in Figure 1, it is obvious that the company have shifted from one 'S' to another – from security to home care systems.

However, as innovators, and to ensure sustainability and continued growth of the business, the directors were soon looking at other business opportunities. They worked with the local community, investigated requirements from older persons and established that there is a need for further healthcare support within their homes, which could not be provided through hardware products – software was needed for this purpose. In rural areas, there is a growing trend towards home monitoring,

with many ratified medical devices available for use, by the older person in the home.

Home monitoring, then, brings with it another need – that of transmitting biometric data such as blood pressure measurement and blood sugar levels to the patient's health professional. General Practice has the potential to change – at times, there may not be a need for the patient, in this case the older person, to travel to the practice to have these measurements taken on a sporadic basis. Alternatively, they can take their own measures and transmit these to medical care. Consequently, ADA-Security directors, in conjunction with another company, developed Local-Health, a prototype for initial testing, with a view to supplying the connected health market.

4.1 Local-Health: Biometric Measurement System

Local-Health (described in Richardson et al., 2016b) allows individuals to text their biometrics from their mobile phone to the local General Practice. The information is coded for reading by the bespoke software where the text is received.

BP – 70-120

Figure 2: Blood pressure reading text message.

As an example, in Figure 2, the text message shows a Blood Pressure (BP) reading of 70/120, which was taken by the patient using a home blood pressure monitor. The receiving system recognises the mobile number from whom the text came, and the data is collected within the General Practice.

The data is compared against an expected reading for the particular patient. If the actual reading is abnormal, an alert is sent to that user, asking them to follow the suggested preventative advice, for example to seek medical advice. An alert can also be sent to individual users if they have not sent their results at the time expected. The General Practitioner can monitor each patient's readings on a regular basis, receive alerts if someone's readings go out of control, and conduct up a follow-up if they deem it to be needed.

Through modifying their healthcare process, the implementation of this simple connected health solution has introduced technology for use within the General Practice,. The patient no longer has to attend the practice on a regular basis, for example, weekly, and yet the Doctor and Nurse can effectively monitor the patient. The consequence of this is that the patient can be monitored without having to leave their own home, while the queues and load for the medics in this rural practice has been alleviated. The General Practitioner can view their patient's data as a line graph e.g. blood pressure over a period of time. Therefore, a trend is illustrated and support making medical interventions in a convenient fashion.

4.2 Local-Health: Potential Business Risks

As time progressed, the company directors recognised a number of potential business risks which arose with Local-Health system:

- Aimed towards individuals and small healthcare practices;
- Market for Local-Health is national;
- ADA-Security expertise is in hardware;
- System developed on a known platform;
- Regulation required for the system.

Aimed towards individuals and small healthcare practices: Once patients have mobile-phone text available they can submit readings, and they are not required to buy Local-Health software. Software cost, therefore, is totally borne by the healthcare practice. The expectation is that this will become a high-volume, low-cost product. Due to high software development costs, the business model is not very cost-efficient.

Market for Local-Health is national: Due to the nature of its hardware products, which includes physical installation of security and social systems, the company has dealt mainly locally and nationally. The market needs to become international. However, going global with a low-cost product can be an expensive undertaking.

Company expertise is in hardware: Those working in the company have a background and experience in hardware installation and hardware attributes. The nature of the new product requires software engineering expertise. This has not been readily available, and development to-date has been sub-contracted. However, without in-house expertise, other business requirements take priority.

System developed on a known platform: Local-Health was to be used by older persons within the local community and it was considered best to develop the product as a mobile-phone text-based system integrating with healthcare practice software. While this works effectively, there is no income due to selling product to individual patients.

Regulation required for the system: Within their hardware business in the security industry, ADA regularly implement regulations. Under European Council (2007) directive, a medical device means

(amongst other things) "software… intended by the manufacturer to be used for human beings for the purpose of diagnosis", and "software … is a medical device". As Local-Health is dealing with the transmission, collection and diagnosis involving patient data and HCPs, it is a medical device. Regulations need to be integrated into the software which is time-consuming and expensive, thus pushing up the cost of production.

5 MAKING THE TRANSITION

Reflecting on the S-Curve (Figure 1), the *Transition* required for ADA-Security to move from their main businesses of security and home care systems to Local-Health is substantial, and the company needs to find a way to overcome the problems identified. They had put many resources into the development of Local-Health to both fulfil a social need and be profitable. This was an opportunity for them to move across to yet another 'S' curve which is vital for the survival of any small company - it is the innovative companies who survive. The leap from security systems to homecare systems was achievable for the company. The leap from their current offerings to the Local-Health software system was difficult.

So how could the company get over this chasm? How could they mitigate the risks they had identified? Considering their options, the directors with the first author of this paper made strategic decisions to change the direction of the product, allowing the company to develop a new innovation, while also presenting opportunities to consider other markets with which they could be involved. The following modifications were made to mitigate the difficulties identified above:

- Seek global market opportunities
- Develop solution for an organisation
- Acquire software engineering skills
- Investigate non-regulated possibilities
- Investigate mobile solutions

Seek global market opportunities: Global opportunities present much larger markets than local, and companies have the ability to expand beyond their local area. For ADA-Security, the installation of hardware systems provided the natural consideration of national solutions. However, moving to a software-based product provides the potential to exploit global expanding markets. In particular, the company recognised that developing countries can offer large populations, therefore much greater sales potential.

According to World Food Programme (WFP) "there are around 800 million people in the world who are malnourished" (WFP, 2016). This includes 200 million children under the age of five suffering from undernutrition (USAID, 2016). A quarter of the world's malnourished children live in India (WFP, 2016), and there are 473,000 malnourished children in Kenya (UNICEF, 2016). Charities and Non-Government Organisations (NGOs) provide health check-ups to diagnose malnourished children and nutrition programmes to resolve the problem.

The development of a system, Global-MN, to support nourishment programs globally has the potential to provide a large market to ADA-Security's software solution.

Develop solution for an organisation: Local-Health was developed for individual use, but, selling to an organisation would be more profitable. Therefore, charities in developing countries were an opportunity that should be explored further, and the development of Global-MN was undertaken. This is an innovative mobile health software application that can store, track and monitor details of malnourished children.

NGOs hire Community Health Workers and health clinics to reach children, test and diagnose them, enrol them into nutrition programmes, and schedule further visits to monitor their progress. The test process normally includes taking the child's height, weight, middle-upper arm circumference (MUAC) and age. To ensure user input to the product, at development stage, ADA-Security teamed with an Indian based charity, Varanasi Children's Hospital, whose work with these children has been hampered by the following problems:

- The manual process currently used to document children's readings is time consuming, thus decreasing productivity of Community Health Workers;
- Retrieval of paper files when a child returns to the nutrition clinic is cumbersome and difficult;
- Paper-based process does not support efficient monitoring of children's progress;
- Community Health Workers are unable to identify previously registered children

As a result, Varanasi were not able to reach and help as many children as they would like. Additionally, there are difficulties in developing reasonable statistics to show how effective the work of the charity is. Varanasi were unable track how well individual children are progressing, nor could they see the success they are having in the field. Having

matched this situation with Local-Health, a decision was made within ADA-Security that Global-MN, would initially support the nutrition program within Varanasi Children's Hospital.

The identified end users are Community Health Workers, as Global-MN software will be downloaded into their phones, allowing them to register and perform screenings on malnourished children. The second end user group are charity and NGO management who ensure that their nourishment programme is effective. Also, to obtain investment from donors, they must demonstrate the effectiveness of their program. Therefore, Global-MN will follow a Business to Business (B2B) commerce model rather than Business to Consumer (B2C) commerce model.

In the first instance, ADA-Security has developed the product for Varanasi Children's Hospital, with plans to expand in the future to other charities internationally.

Acquire software engineering skills: This software-based innovation has potential to open doors to a global market. While, through their business and initial software development, they were in a position to identify the innovation, ADA-Security directors have recognised that they need to acquire software engineering skills and make this product a priority. The skills will ensure that the product they develop is marketable, secure and profitable. Therefore, to bring software engineering to the development process, ADA-Security have partnered with Emergent Research Ltd. (author 5), a high performance start-up software company headquartered locally.

Investigate non-regulated possibilities: While Global-MN must be secure and private, it is not a product that needs to be regulated. It is used to input, track and analyse food-related information – for example, information regarding children who are malnourished and amounts of food. Therefore, it is not a Medical Device and there are no regulations that need to be considered during its development.

Investigate mobile solutions: Local-Health was developed as a text-based system for the reasons stated earlier. However, within the global market for organisations within which Global-MN is being targeted, a text-based system would have many limitations, and a mobile internet-based product is the better option. We have undertaken research which demonstrates that there is internet coverage throughout both India and Kenya, countries where malnourishment programs with children are being undertaken, demonstrating sales' potential. Additionally, the company needed to understand the cheapest and most convenient method by which the data could be transmitted. In rural Ireland, given that there is often limited and sporadic internet access, the solution for Local-Health was to text data via mobile phone. In rural India, internet access is relatively stable, and cheaper than using a mobile phone. Therefore, Global-MH used the internet as its platform. Entering data in this manner means that once a child is registered with Varanasi Children's Hospital, their information is immediately available to the central office. The effectiveness of the program can be monitored on a regular basis. Children who are not progressing as expected can have their food source changed early on in the program, and interventions by the central office can happen quickly. Therefore, infant mortality rates are affected positively in the long-term.

5.1 Global-MN: A Software Solution

Global-MN system is a web-based system with data stored on a secure system in Ireland. This research project was carried out as one action research cycle, allowing the researchers to understand the difference that the implementation of the software made in the field and how the processes could be changed to make a difference. The charity director was trained in system use by author 3. He then travelled to India where he trained the Community Health Workers. They enter data to the system using software running on a smart phone. This data can be aggregated and analysed for Varanasi Children's Hospital allowing management to make informed decisions regarding their malnourishment program..

6 Global-MN: MANAGING MALNOURISHMENT

Using Global-MN, Community Health Workers add children's identification data and a photograph to the system in the rural villages and collect measures to determine malnourishment: MUAC, weight, height and age. Malnourished children are started on a special food program. They return to the clinic every two weeks where their signs are re-measured, further food provided, and updates added to the Global-MN system. Figure 3 shows relevant screen shots from the system. Once data is uploaded, management are provided with data analysis, allowing them to observe progress of children who are on the food program.

6.1 Data Analysis - Individual

Data illustrated is not real data to maintain confidentiality. However, it illustrates how the system can be used for the benefit of tracking the food program for malnourished children.

In Global-MN, data is stored about individual children, including: child ID, which is created by the system when child is first entered, child name, packets given to child per week, start weight, MUAC and height, weight, MUAC and height at each clinic visit, healthcare clinic to which the child is registered, and status, which can be active or discharged. Thus, the system allows the charity to visualise trends for individual children.

As an example, Figure 4 shows the percentage weight gained by individual children based on their start weight. We have highlighted the data for one child whose start weight was 3kg – this child gained 50% of start weight while on the program. Two children weighing over 15kg at the start of the program gained approximately 5% of start weight. Most children gained between 10-25% of their start weight, which is what would be expected from the food program. Figure 5 shows the weight and MUAC gain for a single child during 6 visits to the healthcare clinic. As weight increases, so does the size of the MUAC. This demonstrates that, for this child, the malnutrition program is having a positive effect.

Once a child attends the healthcare clinic, a target weight gain is determined for him / her depending on starting weight, MUAC and height. For the child illustrated in Figure 6, it was expected the child would gain over 4kg in the course of the program. However, it can be seen here that actual weight gain is much lower. With access to on-line real-time data, they can make decisions about this child. It could be, for example, that the child has an underlying condition, in which case she / he can now be sent for medical attention. Prior to Global-MN, this information was not available, further diagnosis was missing, thus perpetuating their problem.

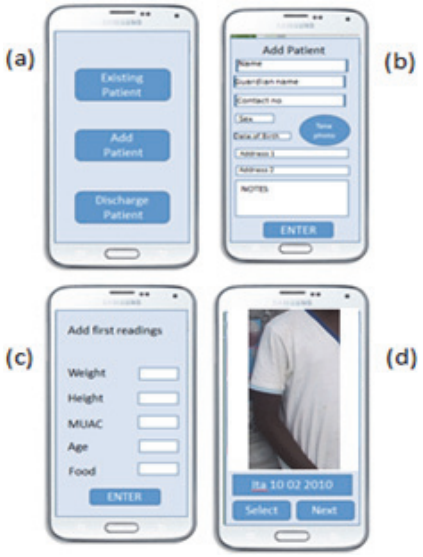

Figure 3: (a) Top level menu (b) Adding child's details (c) Adding information for a child, including number of food packets for that child (d) Information about existing patient including photograph.

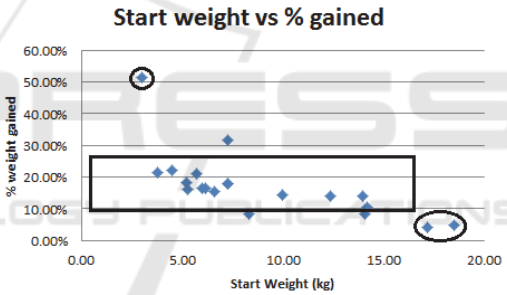

Figure 4: % weight gained based on start weight.

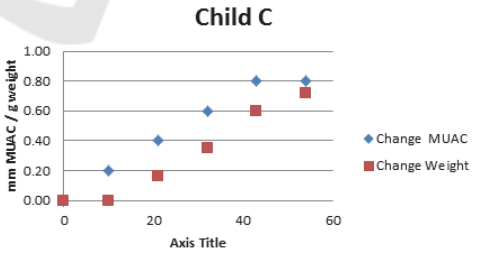

Figure 5: Weight (kg) / MUAC (cm) gained by child over 6 clinic visits.

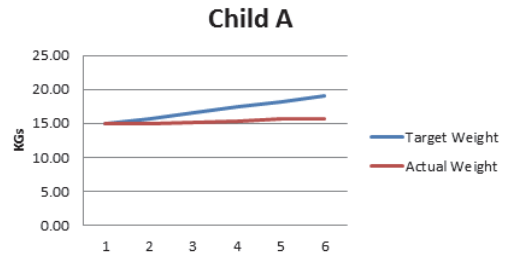

Figure 6: Actual weight gain mapped against Target weight for a child.

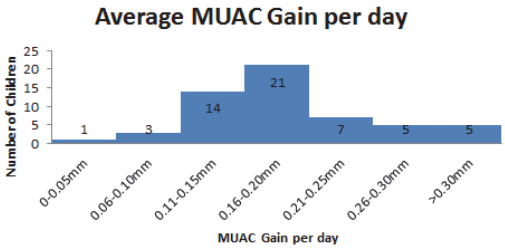

Figure 7: Average MUAC gain per day during program.

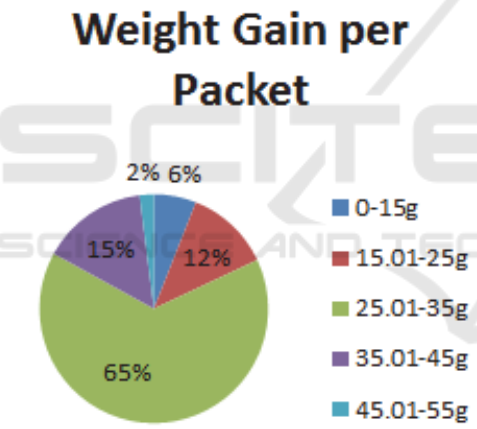

Figure 8: Weight gain per packet.

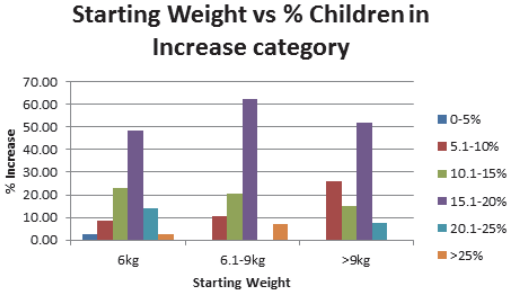

Figure 9: Weight increases mapped against starting weights.

6.2 Data Analysis - Collective

Data can also be aggregated to determine how well the food program is working. This information is used to ensure that children who can benefit are receiving food and that the investment in food is having the maximum required effect. In figure 7, the average MUAC gain per day illustrates that MUAC is increasing through the food program. Thirty-five children (out of 56), 62%, gain between 0.11 and 0.20mm per day. Figure 8 illustrates children's weight gain per food packet distributed. Sixty-five percent of children gained between 25-35g in weight per packet of food. However, six percent of children gained less than 15g per packet distributed. The charity can now further investigate as to why distributed food is not being effective.

Figure 9 shows data for discharged children categorised by starting weight. The expectation is that children's weight would increase by 15-20% of their starting weight. As can be seen in the graph, 48% of children who start at 6kg or less gain this amount of weight. Sixty-two percent of children who are in the 6.1-9kg category gain between 15-20%, while 51% of those whose starting weight is greater than 9kg gain similar amounts. Such aggregated data allows the charity to delve deeper into the success and difficulties within the program.

6.3 Case Study - Summary

To implement Global-MN within Varanasi Children's hospital, Community Care Workers had to be trained in system usage to ensure that data was being entered correctly. Initially, all records were also held on paper, requiring extra work for everyone involved. Trust in the system needed to be developed. At this point, we, the researchers, have been enabled to provide them with both individual and collective data, allowing them to make changes within the charity. For example, if a child is observed as not gaining the expected weight within the program they can be checked for other health issues. The analysis regarding weight per packet mapped against start weight is allowing the charity to consider whether they give different amounts of food to children who start with higher weights. They are collating data which can be used to support arguments for further funding for the charity.

Following the case study, the software is being updated to make it more user-friendly and to provide more on-line and visual reporting that currently exists within the system. Both Varanasi Children's Hospital

and ADA-Security are benefitting from the implementation and analysis of this case study.

7 CONCLUSION

In Ireland and globally, it is recognised that healthcare is a serious problem that needs fixing - "healthcare is the greatest immediate threat to the country" [USA]" (Chase, 2016). Many innovators see connected health in a variety of forms as a means to solving that problem. Innovators must decide the best way to mitigate risks that arise, ensuring that the return on investment is as expected. For the small to medium sized enterprise, and certainly for the very small enterprise, taking risks has a far-reaching effect.

Within ADA-Security, the directors recognised and mitigated the risks being faced by the company. Understanding that their business could grow significantly they sought global market opportunities, identifying that there was a need for data analysis and tracking in programs in developing countries. Their product needed to shift from supporting small to supporting large and from solutions for individuals to solutions for organisation. There are many NGOs working with malnourished children in developing countries, and, supported by a business plan, ADA-Security are now marketing internationally. They recognised that they needed to extend their skill set. Rather than take on new employees, they have partnered with Emergent Research to provide software skills. A further risk was entering the Medical Device software market which is heavily regulated. While being cognisant of regulation, they are developing software without having to obtain European Union or similar certification. In bringing in an established software partner, there are documented software development processes in place. From a technical perspective, the greatest change was that of the platform upon which the product would run - Global-MN is very different to Local-Health.

Throughout their 25 year history, ADA security have been an innovative company, expanding their product base, growing and providing employment in the local community. They recognised an opportunity for innovation, and, in exploiting this, have considered how to overcome the initial risks. In conclusion, Global-MN has given ADA-Security a further innovation opportunity. Considering the five risks and developing mitigation strategies has allowed them to leap the larger chasm between S-curves. As they move forward on their innovative journey, they can take the learnings from Global-MN development to ensure that they can continue to innovate and grow.

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