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1.1.CHALLENGE AND SOLUTIONS

1.1.1. CUSTOMER PAIN AND MARKET OPPORTUNITY



Figure 1 - Type of Injections

Injection is most lazy skills of healthcare professionals. It is one of the most widely used health applications. It is taught in the first year of medical educations of nurses, midwiferys and doctors. Intravenous, Intramuscular, Subcutaneous and Intradermal are the main injection types. In addition, there are intraarterial, intracardiac,

intraperitoneal, intraarticular and spinal intra-canal injection types under the responsibility of the doctor. Injection applications for Mandibular Anesthesia and Tuber Anesthesia are used in the field of dentistry.

Injection is the drug administration, which causes abscess, necrosis, hematoma, ecchymosis, infection, hemorrhage, vascular and nerve injuries, periostitis and pain, if they are not administered to the correct region using the correct method. The most important step for injection to be done correctly and the most difficult step for the student is the correct determination of the region and learning the order of operation steps.



Figure 2- A baby was given a wrong injection into an artery instead of a vein – News Alarabiya

In order to reduce the complications and pain associated with injections, nurses should learn and develop their skills accordingly and students at medical universities should receive a better training, a more realistic one, without involving real patients. In the teaching of injection skills, demonstration method is frequently used for affective and psychomotor education of the student, it is requested from the students to apply the injection on the models. In this training method; students are asked to imagine the region where the muscles are located, the muscle in which the drug is applied, and most of the injection steps. In addition, problem-solving skills can not be gained to students in the face of problems that may occur after drug application. In a study conducted by Ayık et al about drug application errors of nursing students, 10.3% of the students said that they made at least one or more wrong injections to the wrong region. (Ref 1) Also, in a study conducted by Sağkal et al about the knowledge level of the nursing students related with intramuscular drug applications, they concluded that the level of knowledge of the students was moderate and the education given about this subject could not be achieved at the desired level (Ref 2).

When interviewed by Istanbul University Faculty of Health Science, it was understood that the use of simulation in education in Turkey is very poor and there is no simulation laboratory in Istanbul University. It is mentioned that after the standard training without attracting the students, they practiced their first practice on the patient by going to the clinic almost without any practice in the laboratory. In the gold standards published by the World Health Organization, it is recommended to include simulation methods as a teaching method (Ref 3).

The American Association of Nursing Colleges and the National Council of States Nursing State Boards report the use of simulation methods in nursing education (Ref 4, 5). The US National Nursing Association similarly suggests the use of information technologies in order to facilitate learning and support the learning process (Ref 6). Successful health systems require an effective workforce. While many Member States in the WHO European Region have made progress in recent years, a number of health workforce challenges remain that must be addressed to achieve truly sustainable and effective human resources for health. These include supply demand imbalances, geographical maldistribution, inappropriate skills mixes, variations in quality, gender inequality, poor working conditions and the need to improve recruitment and retention.

Injection training methods must improve drastically. Currently, too simple devices or real patients are used, leaving room for medical errors. Covid-19 brings additional challenges: All staff are needed, no time for training but new staff are desperate for training. As up to 75% of Covid-19 positives remain asymptomatic, group training is dangerous. A novel approach is required to reduce risks of incidents in a cost-effective way, improving training and ensuring a real environment without involving a real patient, and to find a scalable training solution for hospitals.

Nurses play a critical role in health promotion, disease prevention and delivering primary and community care. They provide care in emergency settings and will be key to the achievement of universal health coverage. Globally, 70% of the health and social workforce are women compared to 41% in all employment sectors. Nursing and midwifery occupations represent a significant share of the female workforce. Investing in nurses and midwives is good value for money. The report of the UN High Level Commission on Health Employment and Economic Growth concluded that investments in education and job creation in the health and social sectors result in a triple return of improved health outcomes, global health security, and inclusive economic growth. The largest needs-based shortages of nurses and midwives are in South East Asia and Africa. For all countries to reach Sustainable Development Goal 3 on health and well-being, WHO estimates that the world will need an additional 9 million nurses and midwives by the year 2030. (https://www.who.int/news-room/fact-sheets/detail/nursing-and-midwifery)

Nurses and midwives account for nearly 50% of the health workforce. Of the 43.5 million health workers in the world, it is estimated that 20.7 million are nurses and midwives, yet 50% of WHO

Member States report to have less than 3 nursing and midwifery personnel per 1000 population (about 25% report to have less than 1 per 1000), according to the 2017 Global Health Observatory. The Global Strategy on Human Resources for Health: Workforce 2030, the Global strategic directions for strengthening nursing and midwifery 2016-2020 provides a robust WHO strategic response to develop nursing midwiferv it outlines critical objectives. and as (https://www.who.int/hrh/nursing midwifery/en/) Survey on the situation of nursing and midwifery in the Member States of the European Region of the World Health Organization 2009: Table 14 provides an overview of the numbers of nurses and midwives educated and practising in the WHO European Region. The table shows that more than 4.3 million nurses and almost 300 000 midwives are practising in the countries that responded to this survey.

Calculating the total number of nurses and midwives was challenging because some countries reported the same number for both the number of nurses/midwives column and the number of nurses/midwives in the current workforce column. Other countries referred either to the total number of nurses/midwives or the number in the current workforce. These statements reveal the general lack of data on workforce issues in many countries and point to an important aspect for action in the future. In Table 14, the totals were calculated from the 'current workforce' column. Where information was lacking regarding a country's current workforce, the total number of nurses/midwives of that country was chosen instead. (Nurses and Midwives: A force for health Survey on the situation of nursing and midwifery in the Member States of the European Region of the World Health Organization By: Andreas Büscher Bente Sivertsen Jean White 2009) Turkey has 158 Medical School, 203 Faculty of Nursing and Midwifery. In addition, 341 Anatolian health high schools and 166 private Anatolian health vocational high schools in Turkey.

According to the American Association of College of Nursing, as of 2018, there are more than 996 baccalaureate programs in the United States. Of the 688 programs that responded to a fall 2018 survey conducted by the American Association of Colleges of Nursing, total enrollment in all nursing programs leading to a baccalaureate degree was 363,433. A report from the Institute of Medicine recommends that at least 80% of the nursing workforce hold a baccalaureate degree or higher, compared to the current 56% percent. (https://www.aacnnursing.org/nursing-education-programs/baccalaureateeducation)

Simulation has been used widely in the clinical training of health-care students and professionals. It is a valuable strategy for teaching, learning and evaluating clinical skills at different levels of nursing and midwifery education. Literature shows that simulation in nursing and midwifery education provides benefits for both students and patients and can be used to train health professionals about safer and timeous interventions that comply with international recommendations, thereby increasing students responsibility towards clinical practice and improving overall quality of care. This guide aims to support nursing and midwifery educators who want to initiate the use of simulation as an educational strategy. It offers an overview of the main features of simulation, defines key concepts, provides the rationale for simulation, identifies types of simulation, and explains how simulations should be planned, implemented and evaluated. It also provides some recommendations for educators and managers who wish to use simulation in nursing and midwifery curricula or in continuous/in-service education and training. (World Health Organization 2018- Simulation in nursing and midwifery education)

Simulation is an excellent educational strategy for helping nursing and midwifery students in developing ethical attitudes and behaviours, and in applying ethical principles in clinical practice. An example of these principles is respect for the person's autonomy and will (Buxton et al., 2014). Simulation performance outcome measures provide valid assessments of empathy (Bagnasco et al., 2014) and simulation exercises increase selfand cultural awareness (Adamson, 2015). The ability for decision-making in situations where resources are scarce or in extreme circumstances may be trained in simulationbased learning experiences (Buxton et al., 2014). Simulation also contributes to building nursing students' and professionals' identity (Berragan, 2011), relationships with their peers, and expectations of and for future practice (Foronda et al., 2013; Baptista et al., 2016).

Simulation increases students' motivation for learning and improves learning itself (Baptista et al., 2014a). The need for a supportive learning environment is widely recognized in education; simulation provides a unique opportunity to ensure that training addresses affective issues, as it deliberately places the student's needs at the centre of attention and creates conditions for the best teaching practices. Student satisfaction is also referred to as a variable with clear positive results from the use of the simulation (Dillard et al., 2009; Zulkosky, 2010; Foronda et al., 2013). A learning environment that promotes students satisfaction enhances their motivation for study and increases achievement of expected learning outcomes.

Simulation promotes the creation of such environments (Dupont et al., 2009; Mason, 2012; Baptista et al., 2014a). The best outcomes are associated with high-fidelity simulation (Weaver, 2011; Lee & Oh, 2015). The level of satisfaction relates not only to the available materials, instruments and interactive simulators, but also to the trainer's expertise, approachability and communicativeness (Bagnasco et al., 2014).

New technologies like artificial intelligence and virtual reality. Experiential learning approaches that recognize what trainees already know while offering a more immersive, effective and impactful learning experience. (https://www.who.int/about/who-academy) Virtual reality technology is one of the most preferred simulations in medical education simulations since it meets these needs to a large extent and has many important advantages, and it is trendy nowadays.

Over the past 20 days, the number of students affected by school and university closures in 188 countries has nearly quadrupled to 1,57 billion children and youth worldwide. In addition, nearly 60.2

million teachers are no longer in the classroom. Especially in the extraordinary period we are in, the importance of applications that can work independent of location and time has increased.

1.1.2. OUR INNOVATIVE SOLUTION

Simulation types are classified as mannequins or mock-ups, computer aided simulations, simulations used in learning complex functions, and integrated simulations. In the teaching of injection skills, demonstration method is frequently used for affective and psychomotor education of the student, it is requested from the students to apply the injection on the models. In this training method; students are asked to imagine the region where the muscles are located, the muscle in which the drug is applied, and most of the injection steps. In addition, problem-solving skills can not be gained to students in the face of problems that may occur after drug application. In a study conducted by Ayık et al about drug application errors of nursing students, 10.3% of the students said that they made at least one or more wrong injections to the wrong region. (Ref 1) Also, in a study conducted by Sağkal et al about the knowledge level of the nursing students related with intramuscular drug applications, they concluded that the level of knowledge of the students was moderate and the education given about this subject could not be achieved at the desired level (Ref 2).

In the current skill / simulation laboratory, it was determined that the most commonly used simulation tools were skill training mock-ups and models (catheterization, injection, etc.) with 30.05 percentage. (Ref 8) Mannequins or mock-ups are static models. Although the cost is low, the models used are not sufficiently competent to develop skills because they do not respond to the application (Ref 9).

Worldwide VR simulations are very popular in the field of surgery. VR simulations are scalable, cost effective, efficient and maintenance-free solutions. The Johnson & Johnson Institute said that training surgeons using Oculus virtual reality headsets is paying off in big ways, and it hopes that such training will be available worldwide to all surgeons in the future.

Sandra Humbles, the vice president of global education solutions at the Johnson & Johnson Institute, talked about the effective results of VR training during the keynote today at the Oculus Connect 6 event in San Jose, California. Osso VR is the VR business partner that is making the training happen. She said that virtual reality gives surgeons the capability to practice procedures. And an independent study by the Imperial College London showed that 83% of surgeons who trained with VR could then go into the lab environment with minimal guidance. With such training with traditional methods, the percentage So Johnson & Johnson is scaling the effort. was zero. up (https://venturebeat.com/2019/09/25/johnson-johnson-wewant-vr-surgery-training-to-beavailableworldwide/)

A simulation in this area has not been developed due to the lack of adequate labour force. There is no virtual reality application supported by an electronic syringe developed in this field abroad. Our most distinctive feature is our electronic syringe developed with simulation.

Our solution D-Ject is a revolutionary VR training simulator for injections that includes a needle device to simulate injections and to make the training more realistic, a gamechanger for medical education. It can be applied to different type of injections, that includes alerts for wrong injections, pain simulator in case of a wrong injection, and a complete training system indicating how you can inject a patient, procedures to follow, and how to act if something goes wrong. The training device is a combination of software and hardware, and we develop both in order to achieve an integrated system.

Injection training methods must improve drastically. Currently, too simple devices or real patients are used, leaving room for medical errors. Covid-19 brings additional challenges: All staff are needed, no time for training but new staff are desperate for training. As up to 75% of Covid-19 positives remain asymptomatic, group training is dangerous. A novel approach is required to reduce risks of incidents in a cost-effective way, improving training and ensuring a real environment without involving a real patient, and to find a scalable training solution for hospitals.

D-Ject is a groundbreaking technical innovation combined with an ambitious commercial novelty: Medical injection training is performed with a realistic Virtual Reality (VR) device that includes a pain simulator and haptic feedback. For the first time, students receive highly realistic, location independent training without the need of a trainer or patient. Training sessions can be repeated without limit. D-Ject works better than other methods, and trainers can connect online with zero risk of infection. Local medical staff and rooms are available for emergency response, creating an absolutely new market of super realistic remote medical training.

The syringe is a haptic virtual reality controller that can communicate wirelessly. Three patents with KR20120009379A, KR101386338B1, KR20120117222A patent numbers have been identified in this area after our search. These technologies are expensive, and not supporting 6 degree of freedom in virtual reality.



KR101202848B1



KR101386338B1



KR20120117222A

Figure 3- Similar Patents

The device simulates prescription-based syringe sizes (e.g. 30/50/100 units for Enoxaparin) and correct angle (90/45/15 degrees). Its tracking technology precisely determines position and rotation of the needle; the syringe position, grip angle and its depth.

1.1.3. COMPARISON TO THE MARKET STATE-OF-THE-ART

We have carried out a preliminary search to identify our closest competitors. The table below presents the main characteristics of each, showing D-Ject's potential over state-of-the-art solutions:

Features/Characteristics	Mannequins/Mock-ups	Computer Aided Simulations	Integrated Simulations	D-Ject
Productivity	×	×	~	~
Scalability	×	~	×	~
Psychomotor Skill	×	×	~	~
Easy-to-use	~	×	×	~
nteractive	X	×	~	~
Pain Measuring	×	×	×	~
Durability	X	~	~	~
Cost	High	High	Moderate	Moderate

Table 1- Market state of the art comparison

There is no VR simulator for medical training and injections, we found some games related to medical surgery but it's just for fun not specialised in medical training, we also found some tutorials and mockups, usually for this field they simulate the injection through a wearable made from sponges, and it has a limited number of uses. With D-Ject, injections techniques can be trained/learned in an easy-way, erasing and removing the fear and reducing the pain.

1.2. APPROACH

1.2.1. UNIQUENESS IN OUR APPROACH

D-Ject is giving nursing a completely new way to manage the quality and safety that saves time by reducing mistakes and risks by unlocking the full potential of staff assets. D-Ject is the most cost-efficient way for nursing and students within universities to manage the risks of costly accidents and comply with legislation by continuously training nursing and preparing students for their jobs within the medical sector.

VR products typically have a very short refresh cycle and are continuously being developed and upgraded to incorporate new technologies and functionalities. At Negentra we have planned the following developments:

• Apply D-Ject to related medical schools and universities, hospitals, both private clinics and public, institutions, and continue our regional/international expansion;

Opportunities: Negentra has a strong value proposition, Negentra ensures a broader involvement of all employees contributing to continuous improvement of the work place. D-Ject is good for nurses, residents and patients. Our solution will enable staff to fulfil responsibilities and to perform activities to recognised standards of competence on a regular basis, in order to enable health care operators: (1) reduce risks and satisfy legal and regulatory requirements; and (2) Improve and correct techniques applied for injections. The purpose of our solution is to control in a logical and integrated manner a set of activities within the organisation that will assure competent performance in work. The aim of D-Ject is to ensure that individuals: (1) are clear about the competence expected of them; (2) have received appropriate training, development and assessment; and (3) have appropriate experience and maintain or improve their competence over time.

Risks: We have included in our work plan a task to develop an exhaustive risk analysis, but we have already carried out a preliminary assessment of the technical and commercial risks associated to D-Ject final upscaling and commercialisation. The main risks identified are:

- New competitors: It would require a total change of strategy for the competitors to start building a similar algorithm to D-Ject and it would require extensive investments in software development and coding. These types of developments would happen after D-Ject has entered the European markets and we would be able to take advantage of first mover.
- Companies may attempt to copy the business model of D-Ject: Our proprietary algorithms, and thorough IPR policy, makes Negentra's services difficult to replicate.
- Failure to engage strategic stakeholders: Our value chain is mapped, and we have had several meetings with potential collaborators to secure a wide pool of strategic partners.

1.2.2. HISTORICAL EVOLUTION AND RECENT TRENDS

In 1975, Krueger's VIDEOPLACE, the first interactive VR platform, was displayed at the Milwaukee Art Center. It used computer graphics, projectors, video cameras, video displays and position-sensing technology and it didn't use goggles or gloves. VIDEOPLACE consisted of dark rooms with large video screens to surround the user in "VR".

The users could see their computer-generated silhouettes imitating their own movements and actions - the users' movements were recorded on camera and transferred onto the silhouette. Also, users in different rooms could interact with other users' silhouettes in the same virtual world. This encouraged the idea that people could communicate within a virtual world even if they weren't physically close. Nowadays, many companies are developing their own VR headsets, including HTC, Google, Apple, Amazon, Microsoft Sony, Samsung etc.

On the other hand, the use of simulation in medicine dates back to 9th Century when Madame du Coudray4, a French midwife created anatomically correct, life-size mannequin pelvis and mannequin babies and used those to train midwives in childbirth and management of childbirth-related complications. There have been reports of simulation in some form or the other being used in various places at different times. The first mannequin for commercial use is reported to have been marketed in 1911.

D-Ject is one-of-the-kind VR training simulator that offers a realistic environment for all type of injections with pain measuring. and it will optimise the use of simulation in ways that specifically address competencies unique to a given specialty.

2. IMPACT

2.1. ENTERING THE MARKET

2.1.1. TARGET MARKET ANALYSIS

The main reason of the use of simulation is to protect the patient from all avoidable harm and to improve learning, what makes D-Ject the perfect choice for the medical simulation market. Target Market Segments - In terms of geographic market segmentation we aim to focus on the European markets as these are natural extension of our current field of operations. In terms of market segments, we believe that the most potential for our technology lies in hospitals, universities and faculties of medicine where the use of medical training is most critical.

Simulation is used in the education of a number of health disciplines. Medical and nursing schools predominantly use high-fidelity mannequins and low-fidelity mannequins as a way for students to practice clinical skills while standardized patients are used to develop students' communication skills. Standardized patients are also used to assess clinical skills. The United States Medical Licensing Examination uses standardized patients in Step 2 of the licensure examination process to test students' comprehension and application of medicine through replication of cases likely encountered in clinics and doctors' offices. The medical profession also uses simulation for continuing education.

Simulation-based education is a rapidly developing discipline that can provide safe and effective learning environment for students. Clinical situations for teaching and learning purposes are created using mannequins, part-task trainers, simulated patients or computer-generated simulations. As can be seen there are many advantages that simulation will bring into the medical field. However, the limitations of simulation have to be recognised as well, the most important being the lack of valid and

experimental evidence on the utility of medical simulators. However, the most used mannequins and models in education have serious disadvantages. This disadvantages;

- Human systems are very complex and diverse. Lots of information is gained from humans, not instruments. Models and instruments can never match humans completely.
- Poorly designed simulation can promote negative learning. Eg: if physical signs are missing in the simulation, students may neglect to check for these. Simulation based learning may also encourage shortcuts, such as omitting patient consent and safety procedures, and may foster artificial rather than genuine communication skills.
- Participants will always approach a simulator differently to real life. Two common changes in attitude can occur:
- hypervigilance which causes excessive concern because one knows an event is about to ocur
- cavalier behaviour which occurs because it is clear no human life is at stake
- Simulators especially the high fidelity ones are available at considerable costs; both in terms of initial purchase prices as well as maintenance charges. Hence, they are not affordable to many teaching hospitals.
- Incorporating time-slot for simulation in already burdened medical curriculum is difficult.
- Dedicated and exclusive resource personals are not always available. An instructor to learner ratio of 1:3-4 is ideal which is not feasible in the current medical curriculum where each session consists of a batch of 10-15 medical students.
- Some physical findings like skin colour cannot be taught in simulators.
- The simulation models have to be manipulated by facilitators and simulation engineers in such a way as to replicate a physiological response that may be desired under specific circumstances. Manipulating these systems in accordance with desired simulation goals is often cumbersome.
- Instructors may wish to present optimally circumstances according to the abilities of different learners (advanced tasks for proficient students while basic tasks to new or slow learners). This individualized approach is not possible in simulation based teaching. Supporting evidence insufficient: There is only limited amount of good quality evidence on the effect and validity of simulation based training.

A significant disadvantage of the use of simulation in health professionals' education is the cost of sophisticated equipment. An individual high-fidelity simulator costs on average \$30,000. That fee does not include maintenance, training, and technical support. In addition, institutions may purchase ancillary equipment such as vital sign monitors and beds to complement the high-fidelity simulator. Implementing a high-fidelity simulator initially can cost an institution up to \$100,000. An institution will also need space to conduct the simulation and house the equipment . (Simulation and Introductory Pharmacy Practice Experiences- American journal of pharmaceutical education 75(10):209 · December 2011)

Despite the entusiasm of health professions educators for the use of simulation, simulation still has its disadvantages and its critics. The most obvious disadvantage of simulation is that it is not real. No

matter how advanced and sophisticated the technologyis, participating a simulation is not the same for students as working with real patients. Humanistic factors such as emotions and personality and American Journal of Pharmaceutical Education 2011; 75 Article 209. 3 environmental distractions are not conveyed or portrayed the same in simulations as they are in the real world. (Simulation and Introductory Pharmacy Practice Experiences- American journal of pharmaceutical education $75(10):209 \cdot December 2011$)

Stren	gths
35	Dedicated financial support for operating budget
27	Dedicated simulation technician
22	Support from institutional leaders
20	Curriculum development and implementation
18	Instructor training
16	Dedicated simulation nurse/RT educator with protected time
16	Research program
15	Collaboration with other leading centers
15	Dedicated medical director with protected time
15	Engaging health care workers in improving patient safety
14	Simulation operator training
9	Dedicated simulation administrator/coordinator
Barrie	ers
29	Increased financial support
23	Dedicated simulation technician
17	Increased collaboration with other leading centers
17	Dedicated medical director with protected time
15	Instructor training
13	New scenario development
11	Research training
10	Integration of simulation into existing curriculum
8	Increased support from institutional leaders
9	Lack of outcome measurement
8	Simulation operator training
6	Dedicated simulation nurse/RT educator with protected time
9	Dedicated simulation administrator/coordinator

Notes: The numbers listed are the number of simulation centres who responded out of 42. In strengths they responded that they have the item listed, in barriers they responded that each item was a barrier to their furthered success. Abbreviation: RT, respiratory technician.

Table 2 - Strengths and barriers to simulation indicated by centers

The situation of simulation in health education with centers representing 6 countries: In an 42 international questionnaire, financial support was reported as an obstacle by 29 of 42 institutions, instructor education was reported as an obstacle by 15 institutions, integration of the simulation into the current course schedule was reported as an obstacle by 10 institutions, lack of result measurement was reported as an obstacle by 9 institutions, and simulation operator training was reported as an obstacle by 8 institutions. Each simulation center was asked to identify the main strengths and obstacles of its own programs (Table 1), and The most powerful aspects identified within the scope of the study are: support from private financial support, custom simulation technicians and support from corporate leaders. Ironically, the first two obstacles listed were found to need financial support and a special simulation technician. Similarly, trainer training is rated both as a force and as a barrier (Ref 10).

In the scope of the Study Report on Assessment of Skill Training / Simulation Practices in Nursing in the context of Nursing Education Institutions Administrators and Symposium Participants presented by Mr. Prof Dr M. SENDIR in Turkey, it was determined that difficulties in simulation applications are high number of students with 17.90%, cost problems with 14.41%, lack of adequate physical space for the laboratory with 10.91%, the limit of training support of vendor companies with 6.55%, not receiving sufficient technical support from the vendor with 6.12% and the complex structure of the simulation technology with 4.36%. (Hemsirelik Eğitim Kurumları Yöneticileri ve Sempozyum Uygulamalarının Katılımcıları Acısından Hemsirelikte Eğitimi/ Simülasyon Beceri Değerlendirilmesine İlişkin Değerlendirilmesine İlişkin Çalışma Raporu – Tablo 3: Beceri Eğitimi/Simülasyon Uygulamalarında Yaşanan Güçlükler(N=58))

Again, in the context of Nursing Education Institutions Administrators and Symposium Participants presented by Mr. Prof Dr M. ŞENDİR in Turkey, it is observed that the purpose of using simulation applications determined by the related study of Prof Dr M ŞENDİR is skill development and evaluation by 44.91%, and scenarios prepared according to the objectives of the course are seemed to be used as Simulation Scenario Preparation Method.

As can be seen from both studies, the target sector is in an uncomplicated simulation expectation with low cost, low physical space requirement, and which can be used by many students at the same time in the mother tongue. The simulations in the industry are costly, training support of the vendors is limited and they can not provide sufficient technical support. Customer expects user training support and sufficient technical support from vendors.

Health services is one of the areas affected by new technologies very quickly. While the technologies used in the presentation of health services give doctors, nurses and other health workers the chance to do their work with fewer mistakes, they also allow the patients to heal more quickly. In addition, the technologies used are among the key factors to increase service efficiency and improve quality. Virtual reality technologies between these technologies are thought to be significantly effective in future healthcare services. Virtual reality technologies that are clinically approved are widely used worldwide. Virtual reality provides an extra dimension to the person in the virtual environment, giving them the feeling of experiencing it in any situation. In the general sense, virtual reality technology is a combination of real and fiction and imagination. These technologies, which are used in the field of surgical, treatment, rehabilitation and education in health services, have also made it easier for both patients and health workers to do their jobs, and have expanded their use of health services at international level, even if not at national level. Parallel to these, although there are many studies on the relation and benefits between virtual reality and health services in international literature, there are very few studies in Turkish literature.

The global medical simulation market size is projected to reach USD 3.7 billion by 2025 from USD 1.9 billion in 2020, at a CAGR of 14.6% during the forecast period. (Patient Simulator, Task Trainer, Surgical Simulator (Laparoscopy, Arthroscopy), Dental Simulator, Eye Simulator, Ultrasound Simulator, Simulation Software), End User- Global Forecast to 2025)

The global Virtual Reality (VR) in healthcare market size was valued at € 490 million in 2016 and is projected to grow at a CAGR of 29.1% during the forecast period. The growing integration of technology & digitalization in healthcare, increasing healthcare expenditure & focus on delivery of efficient health services, and its significance in training healthcare professionals are some of the key factors driving the increasing adoption of AR and VR technologies.

The global augmented reality and virtual reality in healthcare market is expected to reach \in 3.09 billion by 2023. The growing adoption of Augmented Reality (AR) & Virtual Reality (VR) in medical field, increasing investments in such emerging technologies, and constant developments in healthcare IT are some of the key factors responsible for growth of this market. It provides perfect timing for Negentra to enter the market. Combining our fast market expansion strategy with the increasing demand, will allow us to reach \in 13.29m in revenue 5 years after completing the project (2024).

Further, COVID-19 has an unprecedented impact on medical education worldwide, leading to cancellation of lectures, exams, clinical rotations, and ultimately temporary closure of medical schools. The main reason of the use of simulation is to protect the patient from all avoidable harm and to improve learning, under these conditions what makes D-Ject the perfect choice for the medical simulation market.

2.1.2. TARGET CUSTOMERS AND UNIQUE SELLING POINTS (USP)

Our main target users are faculties of medicine, hospitals and clinics. These users can be reached directly. Users can be reached indirectly via traditional training organisations or even university colleges providing nursing educational programmes. The education of nurses covers a long range of skills. Knowledge of protection and dealing with fires is a significant part.

USPs	Main Economic Benefit
Specific tailoring & high user friendliness	Enables all users, to report directly about competence updates and incidents, increasing transparency, improving reporting and compliance (no price tag).
Single entry point / All in one place	Reduces risk of being sued due the lack of training, eliminate/reduce mistakes
Improving Injections techniques	Increases efficiency, competence and safety resulting of more qualified doctors and risk reduction for unwanted incidents

Table 3- Summary of the main economic benefits and unique selling points [USP] for D-Ject users

2.1.3. COMPETITOR ANALYSIS

Product	(Producer)	Туре	Price	Connection	USP
	GD/HS20E	Mannequins	220 EUR	Needle connected by 2 cables (+-)	Arm with skin color
	BIX-H1T	Mannequins	135 EUR- 878.22 EUR	-	Simple and clear, it is an ideal product for students to practice
and the second s	Labpilot	Mannequins	650 EUR	2 cables (+-)	Transparent Torso Model for Contrast IM Injection Teaching Upper Arm Injection Simulator with Alarm System
	BIX-HS12	Wearable	10 EUR	-	Convenient for training
	eSyringe	VR + e- Needle	690 EUR +15 EUR/M	Wireless	Realistic experience with pain measurement

2.1.4. CONS OF OTHER MEDICAL SIMULATIONS

A significant disadvantage of the use of simulation in health professionals' education is the cost of sophisticated equipment. An individual high-fidelity simulator costs on average \$30,000. That fee does not include maintenance, training, and technical support. In addition, institutions may purchase ancillary equipment such as vital sign monitors and beds to complement the high-fidelity simulator. Implementing a high-fidelity simulator initially can cost an institution up to \$100,000. An institution will also need space to conduct the simulation and house the equipment. (Simulation and Introductory Pharmacy Practice Experiences- American journal of pharmaceutical education 75(10):209 December 2011)

Туре	Description	Examples
Compiler driven	Specific task trainers replicating a particular part of the anatomy.	Intravenous-insertion arms, urinary catheter trainers, airway management heads, central line placement torsos.
Event driven Standardised patients	Actors trained to role-play patients for training and assessment of history taking and physical procedures.	Simulated clinical situations
Hybrid simulation	Combination of standardised patients and part- task trainers	
Computer-based	Uses mouse and keyboard navigation for multiple pharmaco-physiological models	

Table 5- Type of Simulations

Low fidelity Screen based text simulators	Create scenarios with user selecting one of the several responses. E.g. in a scenario involving a patient with severe headache, the user may be offered options such as prescribing an analgesic or getting a CT scan of the head. Simple to construct and are less expensive but they focus on single skills and there is poor immersion
Static mannequins	Used for hands-on practice. E.g. intubation, laparoscopic training or cardio pulmonary resuscitation ('Ressusi' dolls)
Medium fidelity Screen-based graphical simulators	Suited to demonstrate physiological, pharmacological processes. Provide a more realistic representation, are portable, and relatively less costly. These help one to understand the basic concepts but do not confer actual practical skills. E.g. Computer simulation of changes in Blood pressure in response to drug administration(Ex pharm)
Mannequins with mechanical movement	Includes a mannequin and software. Computer-based pictures help confer practical skills Includes 'range of normal variation' E.g. Cardio-pulmonary resuscitation (AMBU Man)
High fidelity simulators	Combine part or whole body mannequins to carry the intervention with computers that drive them to produce physical signs. They are usually designed to resemble the reality. They can talk, breathe, blink, and respond either automatically or manually to physical and pharmacological interventions
Non-physiologic programming	Manually set parameters dependent on operator programming. Parameters need to be reset after intervention
Physiologic programming	Automatic generation of appropriate physiological responses to treatment-interventions in the mannequin allowed. E.g. human patient simulator.

Table 6- Classification of simulation as per fidelity

- Incomplete mimicking of human systems: Human systems are very complex and diverse. Lots of information is gained from humans, not instruments. Models and instruments can never match humans completely.
- **Defective learning:** Poorly designed simulation can promote negative learning. Eg: if physical signs are missing in the simulation, students may neglect to check for these. Simulation based learning may also encourage shortcuts, such as omitting patient consent and safety procedures, and may foster artificial rather than genuine communication skills
- Attitude of learners: Participants will always approach a simulator differently to real life. Two common changes in attitude can occur: (a) hypervigilance which causes excessive concern because one knows an event is about to occur (b) cavalier behaviour which occurs because it is clear no human life is at stake.
- **Cost factor:** Simulators especially the high fidelity ones are available at considerable costs; both in terms of initial purchase prices as well as maintenance charges. Hence, they are not affordable to many teaching hospitals.
- **Time factor:** Incorporating time-slot for simulation in already burdened medical curriculum is difficult.
- Infrastructure: Dedicated and exclusive resource personals are not always available. An instructor to learner ratio of 1:3–4 is ideal which is not feasible in the current medical curriculum where each session consists of a batch of 10–15 medical students.
- Technical difficulties: Some physical findings like skin colour cannot be taught in simulators.
- **Programming difficulties**: The simulation models have to be manipulated by facilitators and simulation engineers in such a way as to replicate a physiological response that may be desired under specific circumstances. Manipulating these systems in accordance with desired simulation goals is often cumbersome.
- Learner specific teaching not possible: Instructors may wish to present optimally circumstances according to the abilities of different learners (advanced tasks for proficient students while basic tasks to new or slow learners). This individualized approach is not possible in simulation based teaching. Supporting evidence insufficient: There is only limited amount of good quality evidence on the effect and validity of simulation based training.

Resource: Simulation and Introductory Pharmacy Practice Experiences- American journal of pharmaceutical education 75(10):209 · December 2011

2.1.5. KEY BARRIERS TO MARKET ENTRY

Negentra will have to overcome several difficulties to achieve a full market penetration. Some of the barriers were identified in the table below. Our strategy to overcome barriers is described in Table 5 below.

Barriers	Strategy for overcoming barriers
Difficult scaling to new countries	Use our present stakeholder network and the results of the business plan to implement our go-to-market strategy Get local key hires right
eSyringe may needs specific certificate to be deploy in nursing and care institutions	Identify as early as possible requested certificates to immediately start the process to grant eSyringe
Need for new skills	Negentra team are experts in the field (see section 4.1). eSyringe will use existing contacts with important developers and institutes on VR for talent recruitment.
New facilities	eSyringe will adapt its operations to the demand, reaching to the proper agreements with stakeholders to reduce the investment in physical facilities.

Table 7- Barriers for successful market launch of D-Ject

2.2. BUSINESS MODEL

2.2.1. OVERALL BUSINESS STRATEGY

D-Ject's strategy is based on seeking competitive advantage in a new market reducing its reliance on the medical simulation industry. As a small niche company, we have relied for too long on our established business while we see extensive market potential outside of our current field of operations. Therefore, it is our aim to pursue a market development strategy and introduce our technology into new markets.

2.2.2. VALUE CHAIN AND WIDER STAKEHOLDER ANALYSIS

The below Figure shows our value chain with the identified primary and support activities – both are required for us to provide and retain our differentiation advantage on the markets. The key value and differentiation creating activities for us are within design and engineering, together with customization and assembly of our products. (see Figure 4).



Figure 4 - Overview of our value chain

In terms of value chain and key stakeholders for a successful commercial exploitation, it is our engineers that are at the core of both of those concepts. Our internal know-how amassed over 20 years of operations, together with a wealth of knowledge regarding engineering problems and solutions within this field is what sets us apart from the rest of the market saturated with subpar standardised solutions. We are currently looking into expanding our engineering team to bring in more ideas and to strengthen this core value proposition that will be key for future commercialisation of our product.

2.2.3. BUSINESS MODEL & PRICING

The price of our solution is \notin 690 per unit as upfront payment. Our business model is based on upfront Payment and a monthly/yearly subscription, the monthly price is \notin 15 per license. We are also including new updates for the VR simulator with more features. To present our business model, we use the strategic management and lean start-up template Business Model Canvas initially proposed by Alexander Osterwalder (see Figure 5 & Annexes).



Figure 5- D-Ject Business Model Canvas

2.3.FINANCING

2.3.1. OWNERSHIP AND CAPITAL STRUCTURE

Negentra is a Turkish SME established in Jan 2018 owned by Gürcan Serbest, it's specialised in delivering innovative VR- solutions received its first investment of €32,000 from the TÜBİTAK.

2.3.2. FINANCIAL IMPACT AND GROWTH POTENTIAL

The primary sales effort will be direct sales through our already well stablished sales organisation. Our estimate for market share achievement in Year 5 post launch is 0.43% of €3,09 billion. Considering the extent of market potential, business type, the level of human expertise required for full-time employees and considering the location of our headquarters and manufacturing we find the below forecast very realistic. However, when the achieved market share exceeds our estimate we aim to reinvest the extra revenue to increase the rate of expansion. Therefore, establishing and assessing market sizes and potential demand for D-Ject project is the cornerstone of the Feasibility Study. For this reason, we will be reviewing our forecast as we gather learnings from the Feasibility Study.

Estimated growth	Pre-launch	Year 1	Year 2	Year 3	Year 4	Year 5
Revenue from sales (€)	0	61,800	1,854,000	4,635,000	7,107,000	13,287,000
New market share EU (%)*	0.000	0.002	0.06	0.15	0.23	0.43
Accumulated employment	0	6	15	20	25	31
Operating cost (€)	32,000	53,400	97,600	161,000	198,000	214,000
Net profit from sales (€)	0	8,400	1,756,400	4,474,000	6,909,000	13,073,000
Accumulated profit (€)	-32,000	-23,600	1,732,800	6,206,800	13,115,800	26,118,800
ROI D-Ject (ratio)**	n/a	-1.02	+0.17	3.21	7,91	16,79

* Market volume: €3.09 billion. **Return of Investment (ROI) calculated as (profit-

investment)/investment.

Table 8- Growth Forecast

The cost estimate is based on: 1) Full Time Employees (FTE) required at the end of Phase 2 (year 2021) growing towards 31 people post-launch in year 5 to oversee manufacturing; 2) product adaptations; 3) sale prices according to the most conservative average figures; 4) operation cost (equipment and maintenance); and 5) marketing. We have estimated a $\in 1,503,429$ investment for these calculations, which is calculated as the sum of the estimated investment for Pre-project ($\in 32,000$), Phase 1 ($\in 71.429$), Phase 2 ($\in 1,100,000$) and Phase 3 ($\in 300,000$). This conservative estimation shows that D-Ject will reach positive net income and break-even in year 2 (see ROI for this year in Table 6). The Feasibility Study is critical for assessing the ability of our concept to fulfil the market need through analysis market demand and costs, to arrive at the detailed business plan where we will refine our pricing model and revenue stream(s).

2.4. IPR, LEGAL FRAMEWORK AND FREEDOM TO OPERATE

The IPR plan is to develop and protect all aspects of D-Ject. The protection will follow existing, successful IPR protection strategies viz. 1) Protect the primary assets identified in the form of software, its underlying ideas, the database and proprietary methods by copyright, whereas the ideas and concepts underlying the creation of this software, and the algorithm model and methods it implements constitute trade secrets; 2) guarantee our FTO noting that a preliminary FTO analysis has not shown major obstacles for D-Ject. An in-depth analysis will be conducted during this feasibility study; 3) make strenuous efforts to safeguard any other IP arising from D-Ject, such as protecting trade secrets through setting confidentiality agreements in place with all our employees, including founders and co-Investors; 4) define details on this process to clarify all the steps required during this feasibility study

in the IP management study; 5) protect our competitive advantage by focussing on continuous innovation to ensure our lead in the market; 6) perform an extensive search of the CORDIS project database for similar EU-funded projects to collaborate/follow; 7) include a network patent analysis in the subsequent development. Trust and data security are therefore essential for our Business model. We pay special attention to ICT security, and the management of confidential business information. Besides EU law, each country has its own.

D-Ject plans to expand its business development department and use several tools, as the settlement of new distribution channels, advertising, workshops and demonstrations to get new potential clients. Our geographical expansion will be done through licensing, D-Ject also foresees to extend D-Ject to other sectors where similar needs have already been identified.

The dissemination activities will continue in conjunction with a focused sales and marketing effort to reach global growth. We expect raising €1.5M within 2 years of concluding the project to expand the sales efforts.

3. IMPLEMENTATION

3.1. ORGANIZATION DESCRIPTION



Negentra (NExt GENeration TRAining) is a Turkish SME focused on developing disruptive, highly innovative software and hardware technologies. It aims to produce Virtual Reality simulations and Extended Reality for medical training.

Negentra's mission is to make it possible for everyone to deploy and take full advantage of emerging Virtual Reality and Augmented Reality solutions and to expand education to everyone and everywhere and to bring education. technologies to a higher level. We achieve this by offering full turnkey solutions.

O OCUIUS ISV PARTNER

Negentra has been selected to be a part of Oculus Independent Software Vendors (ISV) Program. The

Oculus ISV Program looks to accelerate customer adoption of VR solutions built for Oculus enterprise products, working with enterprise developers and software companies.

Negentra was accelerated by InvestHorizon and has InvestHorizon Accelerated labels. The InvestHorizon Accelerated label is for selected deep tech companies from the accelerator programme to facilitate series A funding.



The Negentra team and their Advisory Board are experts specializing in medical training VR and building successful businesses. Their numerous awards prove their technical experience and business acumen. Combined, they undoubtedly have the necessary track record, technological and business skill set as well as high motivation to make D-Ject a success everywhere and specifically in the target market.

With their knowledge and both industrial and scientific capacity, Negentra will be able to undertake a further collaborative RTDI project and is very eager to do so.

The main team consists of:

- **CEO and Founder, Project Coordinator: Mr. Gürcan Serbest:** Mr. Serbest holds an MSc in Computer Engineering from Hasan Kalyoncu University and a BSc in Business Administration from the Anadolu University (Turkey). He is a Serial Entrepreneur, and experienced developer his background in Business and Computer programming allows him to work for different organisations until he decided to open his first company IMECE in 2014 and Negentra in 2018. He was selected as one of the heroes of the 400 million dollar game exports by TurkishTime Economy Magazine in 2016. (http://www.turkishtimedergi.com/dijital-girisim/15104/)

He've also organised +15 seminars at universities, lecturing about Unity3D with more than 1100 attendants (Since 2008). He is an Unreal Engin 4 Founders Club member. He is a respectful member of the Game Developers Association in Turkey, with +10 years of experience developing games and simulations, and +4 years of experience managing companies.

- **CTO** and Technical Manager: Batur Alp Akgül: Mr. Akgül holds a Master degree in Management Information Systems and an associate degree in computer programing, both from the University of Ahmet Yesevi (Turkey), and a master degree in Electronic and Computer Engineering from the University of Hasan Kalyoncu (Turkey). He has more than 15 years working experience managing the Information Technology Department within three private national companies as systems engineer and IT staff. Expertise in developing and maintaining IT system to Support business activities, which included but not limited into implementing & troubleshooting Microsoft- Linux systems and network (LAN) and servers, Installation and administration: Information Systems and Network Service Technologies, and Windows-Linux Security, Fundamental & Development, Windows-Linux server and domain system configuration, and broad experience with other software.

- Chief Business Officer: Mr. Burçak Acır: Mr. Acir holds a BA degree in Public Administration from Uludag University in Turkey, and a BA (Hons) degree in Business Administration with a major in Marketing from DeMontfort University in UK. He has also an Executive MBA degree from Copenhagen Business School in Denmark. He has 20+ years of hands-on business development

experience with proven record in global markets. After founding his own consulting firm back in 2016 with a focus on technology and engineering, he joined Negentra as a chief business officer since 2019.

- Software Development: Mr. Selim Duru: Mr. Duru holds 3 degrees in Engineering in Electrical and Electronics from different universities in Turkey, he had a deep knowledge and experience in different programming languages (C# and C++), Embedded system design and maintenance, Pcb design and Fiber optic communication systems. He spent +9 years working in Electronic Communications (since 2009) in Telmar Electronik and Durutech Machine Software Ltd.

- **R&D: Prof. Neslihan Özcan:** Ms. Özcan holds a Ph.D. and a MSc. In Nursing and Mental Health both from the Faculty of Health Sciences (Istanbul University). She has +23 years of experience in Research, from 1996 when she started as Teaching Assistant (Istanbul University) and became Prof. in 2020.

- **Project Commercial Manager: Ms. Ayça Zaman:** Ms. Zaman is in charge of marketing and sales, from strategy to planning and implementation coordination. She has over 10 years of experience in online marketing, managing the business deals with hardware/software companies, contracting new partners, contacting with media and tech/video games press to promote deals and new partnerships. She is the coordinator of Game Developers Association of Turkey since 2017 and also worked as an Indie Evangelist at Quixel/ Epic Games in 2019-2020. She worked as a Country Manager for Kinguin Ltd (2016-2018). She also worked for Red Bull in Turkey (2016), and digital product development and business optimization in the telecom, travel, retail, banking and language services sectors. Ms Zaman has a degree in French Language & Literature from the Istanbul University (2003- 2009), She is a Jury member of Bilgi University Game Jam, Game and she is also giving lectures in panels about marketing, sales and video games industry. Ms Zaman will be the project Commercial Manager. She will be responsible for project innovation activities, go-to-market activities and end-user communication, by translating the business plan into a commercialization plan focused on exploitation of the project results and performance of pre-commercialization activities.

- Industrial Designer: Ms. Gonca Çamkerten: Gonca has +8 years of experience in Product Design from industrial products to digital. She has worked with several startups as a project-based designer and help them to succeed in their product journal. Also she's a design thinker who voluntarily executes OpenIDEO and PechaKucha local chapters & co-founder of UX'minimal. She will help D-Ject to develop the right user experience with the right industrial product and production model.

3.3.BOARD OF ADVISORS

- **Prof. Dr. Gholamreza Anbarjafari: Simulation Consultant:** Mr. Anbarjafari is one of the most important computer vision experts in the world, he is a professor and head of iCV Lab focusing on applied image processing, computer vision and computer graphics. He will help Negentra to improve the hand pose recognition within the D-Ject project.

Prof. Dr. Volkan Arisan: Dentistry and Health Systems Consultant: Ms. Arisan holds a Ph.D. and a MSc. In Dentistry both from the Faculty of Dentistry (Istanbul University). He has +22 years of experience in Research, from 2004 when he started as Research Fellow, Clinician (Istanbul University) and became Prof. in 2017.

Awards:

- 2007 ICOI (International Congress of Oral Implantologists) World Congress, San Francisco California, "Second Place Award" by the oral presentation of the study "Injectable calcium phosphate cement as bone graft material around peri-implant dehiscence defects: a dog study"
- 2006 EAO (European Academy of Osseointegration), Barceloba, Spain, "Travel Award" by the oral presentaion "The effect of injectable calcium phosphate cement on the bone- anchorage of titatium implants: a dog study"
- Dr. Ertu Unver: Innovative Design Consultant: Mr. Unver has +35 years of experience in R&D&I, product design, 3D digital Design and Mechanical Engineering. He entered the design industry when he started working for a UK based Industrial Design consultancy in 1995 as designer & CAD/CAM manager. In 1999, He was appointed as Senior Lecturer at the University of Huddersfield, teaching on Product, Industrial and Transport Design courses. He extensively used various technologies including 3D printing, prototyping, 3D scanning, motion capture, design optimisation and analysis. his recent research involves the use of rapid manufacturing systems, 3D laser sintering & Stereolithography, 3D printing technologies for Rapid Tooling, application of 3D laser scanning process for innovative product development and VR systems for product realisations. His recent works include: Development of medical products, innovative idea generation, design for manufacturing support & knowledge transfer for local, national companies, application of polygonal & graphical algorithm modelling /programming technologies, software development of randomly mutating shapes & 3D meshes for building of complex craft forms. He has published over 120 papers including peer review journal articles, conference papers, project report, exhibitions.

Awards:

- Winner of Yorkshire and Humber Healthcare Partnership with Academia Award, (24th Feb 2016), Royal Armouries Hall, Leeds, UK,
- Winner of West Midland Medilink Innovation Award (14 Jan 2016): ,
- Winner of Medtec Ireland Exhibitor Innovations Accolade Award (4-5 Oct 2015),
- Insider's 2016 Made in Yorkshire Awards (4/Mar/2016), Paxman Scalp cooling system is presented for Healthcare Manufacturer Award
- Dr. Mustafa Özçınar: Medical Consultant: Dr. Özçınar has been practicing family medicine for +13 years. He was in charge of the public health service unit and he was the director of the public health center.
 - o Fatih Municipality Health Directorate, Istanbul In charge of the Public Health Services Unit
 - o Fatih Municipality Health Directorate, Istanbul- Director of the Public Health Center
 - o Pendik Municipality Public Health Center, Istanbul- Family Medicine Unit
 - o Family Physician, 21st Family Health Center, Karşıyaka Izmir
 - Dokuz Eylül University, Field Trainer Active role in the organisation of the transition process of primary health care system to Family Medicine Model in Izmir, 2006-2007
 - Izmir Health Directorate, Education Coordinator in the transition to the practice of Family Medicine, Konak İzmir, 2005-2007
 - T.C. S.B. Dr.Lütfi Kırdar Kartal Education and Research Hospital, Istanbul Family Medicine Specialty Training 2001-2005

He will Help Negentra with the VR injection techniques and pain measurement.

- Assoc. Dr. Murat Aşçı: Medical Consultant: Mr. AŞÇI holds a Ph.D. and a MSc. In Orthopedics and Traumatology both from the Faculty of Medicine (Gaziosmanpasa University). He has +13 years of experience in Research. He will help to continuously improve the D-Ject VR environment and techniques to offer a realistic training. He is currently working in Eskişehir Acıbadem Hospital as a specialist in Department of Orthopedics and Traumatology

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- Assoc. Dr. Serdar Çelik: Sound Design Consultant: Mr. Çelik has +16 years of experience in Music Technology and Max/MSP based microtonal interface design, MIDI and electronic. He has several researchs published in International journals and international proceedings. He will help D-Ject and advise Negentra to achieve a real experience for the users by offering the best sound experience.
- Mr. Miguel Motos Javaloyas: Technical VR / Simulation Consultant: Mr. Motos has +8 years of experience in Electronics and systems. +9 years of experience in sales of Plotters, xerox engineering systems. He has experience in training and in technical areas (Since 1979). He worked for Hoogovens (The Netherlands 1979-1981), for Brokers BV (1981-1983), Econocom Distributie BV (1983-1988), Xerox Engineering Systems (1988-1989), Grupo Union Naval (1989-1991), Director of Simulation and VR in INGEVIDEO (2009-2020) and now he is Director Of Business Development at Target3D Iberia. He will advise Negentra from both: sales and technical points of view.
- Mr. Uğur Kafadar: Electronic Systems Consultant: Mr. Kafadar after working +12 years as an electronic design and software development engineer in R&D projects that require high technology in the defense and white goods industries, he has worked as an executive and coordinator in many international and national R & D / innovation projects, including the leading brands of Turkey and the world. He will consult Negentra to improve the electronic design quality.

3.4. TEAM AS A WHOLE

The Negentra team, together with the Advisory Board, are a team of experts specializing in medical training VR. The numerous awards they have received collectively proves their technical experience and also their business acument. Their skills and core competencies lie in their very wide experience of dealing with their product and from over two decades of experience dealing with clients and VR solutions.

Combined, they undoubtedly have the necessary track record and technological as well as business skill set as well as high motivation to make D-Ject a success everywhere and specifically in the target market. With their knowledge and both industrial and scientific capacity, Negentra team will be able to work effectively undertaking this project and is very eager to do so.

Negentra is gender neutral. We contractually ask any subcontractors to also be neutral regarding gender, race, ethnicity, age, sex, and religion. Furthermore, we focus on gender equality by removing the gender pay gap, by promoting equal opportunity in the workplace regardless of gender, and by respecting diversity in order to ensure that people are valued. We are aiming at a 50-50 gender balance of our talented and skilled teams.

3.5.PARTNERS

Negentra has a strong partner network from all over the world. Partners who will work closely within the scope of the project can be seen in the figure. Please see the annexes for the letters of intent of these partners. For details of cooperation with partners, please see the Technical Concept Paper.



Figure 6- Partners

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5. ANNEXES

- Detailed Commercialization Work Plan
- Risk Management And Contingency Plans
- Business Model Canvas
- D-Ject USP & Future steps
- D-Ject Market Size (TAM-SAM-SOM Approach)
- Letter of Intents

DETAILED COMMERCIALIZATION WORK PLAN

There are more than 15 national and international institutions that we cooperate under this project. In addition, our cooperation with these institutions and organizations will continue increasingly. The letters of intent received on various occasions are presented in the annex.

Cooperation will be made with Inge Video which company is one of the leading simulation products seller of Europe for enter the European Market. It will benefit from the global business network of Game Developers Association of Turkey, which we are one of the founding members. Letters of intent are presented in the annex about that.

Negentra has become one of the 12 most successful health startups selected for EurasiaStart. Health IT Conference and Exhibition is one of the most important health sector events in the world organized within the scope of HIMSS Eurasia. EurasiaStart is a network platform that does not have a leadership, subordinate, superior relationship in the ecosystem but acts only in the focus of producing information with the concept of ask, discover, produce, and generating benefits to humanity. We found opportunity to receive valuable feedback from industry leaders, investors and mentors from 30 countries about the product and technology we developed within the scope of EurasiaStart. We will benefit from the EurasiaStart for verification and commercialization.

Negentra became one of the companies accepted to SelectUSA Tech 2020 organized within the scope of SelectUSA Investment Summit. While explaining our technologies to venture capitals and corporate investors, we will also have the chance to show our product to the participants. It will be an important advantage for us especially for entering the America market. In addition, Negentra has been accepted to the Nar Vertical Accelerator and Commercialization Program, TechUp 2018 Accelerator Program, TTGV 250K Accelerator Program, ICUBE Accelerator Program, TechUp+, Bigg+ and InvestHorizon. We have benefited from many mentoring services in these programs. Networks of these programs will be used for commercialization.

Negentra has been selected to be a part of Oculus Independent Software Vendors (ISV) Program. The Oculus ISV Program looks to accelerate customer adoption of VR solutions built for Oculus enterprise products, working with selected enterprise developers and software companies.

We are currently in cooperation with Lava IP International market to enter the U.S market. In addition, similar work is done with Sisma International on entering the European market. Within the scope of cooperation with these companies, it is envisaged to achieve the following goals.

- Identifying at least 200+ relevant prospects across the target markets, using Sisma International & Lava IP International's CRM system, our target list and other primary and secondary internal and external market sources, that fit the right profile as a potential client for Negentra's Medical Simulation & Extended Reality Technologies.
- 2) Identifying who makes technology and innovation-related decisions at these target companies wherever possible - it is expected that relevant prospects may include (but not be limited to) CEOs, VPs, Heads of Medical Technology, Heads of Imaging, Heads of Patient Care etc.
- Assessing these individuals willingness to learn more about Negentra without mentioning Negentra by name at this point.
- 4) Get approved documentation about Negentra to people who request more information with the key description of Negentra and info packs/PDFs to be approved by Negentra
- 5) Gauging how we can best engage with each potential client that shows an interest in our Medical Simulation & Extended Reality Technologies, including details of how these companies and organizations would ideally like to work with us, and also including any potential deal breakers (which we should then be able to decide whether or not to be worth overcoming.
- 6) We would expect to uncover at least 10 companies and/or organizations that would be interested in learning more about the benefits of working with Negentra and it could be more, in which case there would be no extra charge in other words we will aim to exceed the minimum of 50 meetings if possible on a best-efforts basis.

We propose to approach systematically by creating work packages with the scope consistent with the expected objectives.

During and following our pilot experience, our overall commercial strategy will be to achieve rapid market uptake by offering our product to the key stakeholders in the VR for medical training industry. We will target and transform potential companies, into a paying client after a successful pilot performance.

The work packages are what is needed to put D-Ject into the target marketplace. All of the other pieces are in place including a highly skilled and motivated team and proprietary technology. The packages are:

WP1: D-Ject technology valuation calculation and analysis of technology partnerships.

Description: The goal is to calculate a valuation of the technology through viable methods such as discounted cash flow (DCF), market comparisons, benchmarking, ratings or similar. As for technology partners, we will focus on local target market partners in proximity to large hospitals and universities.

Task 1.1: Create valuation based on market comparison / benchmarking / DCF
Task 1.2: Compare different valuation approaches and calculate the most plausible one.
Task 1.3: Research and analyze potential hardware partners.
Task 1.4: Research and analyze potential software partners.

Deliverable 1.1: Technology valuation analyses. **Deliverable 1.2:** Technology partners report.

WP2: Small scale proof of concept awareness (trial and assimilation, further RTDI preparatory work).

Description: The goal of this Work Package is to create awareness for a small-scale proof of concept in the target market. This consists of a small-scale trial with local partners and interested parties and will partly lead to an assimilation of our device. Furthermore, the steps will prepare our further RTDI activities. As collaborative partners, we will contact clinics and universities with medical schools.

Task 2.1: Identify highly visible accounts in the target market.

Task 2.2: Create partnerships with accounts.

Task 2.3: Run small scale trials.

Task 2.4: Create awareness using PR, marketing etc.

Deliverable 2.1: Report on small scale proof of concept.

WP3: Definition of a future international cooperation RTDI Project for co-creation or technology adaptation with Lava IP International and Sisma International.

Description: At this point, together with Lava IP International and Sisma International we will have standing collaborations with universities and hospitals due to the small-scale proof of concept awareness WP. In this WP, we will get these partners on board to define future cooperations with them. Additionally, we will research potential partners locally and internationally, in order to create the most potent RDTI follow-up project possible.

Task 3.1: Research potential international and local universities and hospitals.

Task 3.2: Contact potential cooperation partners.

Task 3.3: Draft potential future cooperation projects for co-creation or technology adaptation.

Deliverable: Report on future international cooperation RTDI Project.

WP4: Market quantitative analysis (real, potential, tendencies) and business related social and cultural best practices identification and implementation planning.

Description: To prepare the best possible market entry in the target market, we will create thorough market intelligence by conducting a quantitative market analysis. In order to analyze the scenarios, a literature review as well as expert interviews will be conducted. For tendencies, we will hold interviews with industry experts and players. Planning business related social and cultural rules will be important for a successful market activity. In the US, there are certain business rules and norms that are necessary for conducting business smoothly. We will hold interviews with local potential target customers to get accustomed to our target group specifically.

Task 4.1: Analyze real scenario / potential scenario / tendencies scenario.

Task 4.2: Preliminary research on social and cultural business norms and etiquette

Task 4.3: Conduct interviews with local potential target customers.

Task 4.4: Create a report on relevant social and cultural best practices and how to implement them within Negentra.

Deliverable 4.1: Market analysis report.

WP5: Analysis of potential partners for distribution and marketing, and analysis of potential suppliers. Focus on hospitals, universities, and medical training organizations for distribution and marketing. Focus on local suppliers for supply chain optimization.

Description: To make sure that both our distribution and our supply chain are agile and successful, we will analyze potential local partners. In case of distribution and marketing, we will seek direct distribution partners as well as public relations experts, as these are the most effective channels for our business model. As for suppliers, we will try to find local suppliers and follow a second-source approach in order to always have back-up suppliers.

Task 5.1: Analyze potential direct distribution partners, PR partners, marketing partners.Task 5.2: Research potential local suppliers and create scoring system

Deliverable 5: Report on potential partners and suppliers.

WP6: PESTLE Analysis (social, economic, environmental, technological and legal issues).

Description: This is a summarizing and over-reaching category which covers any gaps in the aforementioned work packages and also aligns the internal structure with external needs.

Task 6.1: Analyze political dimension
Task 6.2: Analyze economic dimension
Task 6.3: Analyze social dimension
Task 6.4: Analyze technological dimension
Task 6.5: Analyze legal dimension
Task 6.6: Analyze environmental dimension

Deliverable 6: PESTLE Analysis report

RISK MANAGEMENT AND CONTINGENCY PLANS

We have identified several potential risks, and designed mitigation measures for each of them to ensure a successful implementation of the project. During each assessment, risks are scored according to likelihood (L, 1-10), severity (S, 1-10) and the risk level is assessed as LxS: Medium/High and High levels (50-100) = Mitigation activities before continuing; Medium level (21-49) = Activity may be conducted but take actions to control severity and/or likelihood; Low/Medium and Low levels (1-20) = Acceptable risk. The team involved in the day-to-day running of the D-Ject project will directly contact the Project Coordinator, Mr. Gürcan Serbest, to ensure that corrective actions are taken at an early stage. Moreover, Lava IP International and Sisma International are global consulting firms specialized in Risk Management. They will assist in anything related to risks for our project.

WP1

- Description of Risk: D-Ject technology does not perform as expected in the valuation and technology partner matching.
- Risk Score: L 2 X S 8 = 16
- Proposed Mitigation Measures: Successful results have already been obtained and proven in home market use. The Project Coordinator will follow the entire valuation to ensure proper technology functionality.

WP2

- Description of Risk: Small scale proof of concept not performing as well as expected - Risk Score: L 3 X S 9 = 27

- Proposed Mitigation Measures: Successful test runs in the home markets have shown that D-Ject does work. As the proof of concept in the target market will be based on home market technology, it is expected to work equally well. The Project Coordinator will closely follow and support the proof of concept, ensuring issue-free work.

WP3

- Description of Risk: No collaborative partnerships can be formed.
- Risk Score: L 3 X S 6 = 18

- Proposed Mitigation Measures: Lava IP International and Sisma International are seasoned consulting firms with local offices in the biggest political, technological and business hubs in the US. In the unlikely case that no partnerships can be found, ControlRisks vast network will be tapped. Moreover, internationally hospitals and universities have already shown interest in D-Ject. Some are based in the US and they can be contacted as a backup plan.

WP4

- Description of Risk: Failure to engage local target customers for interviews on social and cultural best practices.

- Risk Score: L 4 X S 4 = 16

- Proposed Mitigation Measures: In our network, we have strong relationships to US citizens in the medical sector. Should we fail to engage local target customers, we can always interview people from within our network who match the criteria closely.

WP5

- Description of Risk: No local suppliers available for hardware or software components.

- Risk Score: L 2 X S 7 = 14

- Proposed Mitigation Measures: As numerous hardware manufacturers are located in Asia; we can always include them in the supplier analysis. The downside of sourcing from Asia would be longer delivery times but with good supply chain management that will pose no problem.

WP6

Description of Risk: Due to the current Covid-19 pandemic, the fast development in the real world
 for example economically – cannot be analyzed as it greatly differs from the near past. Our
 PESTLE analysis might not be accurate in light of the pandemic.

- Risk Score: L 6 X S 8 = 48

- Proposed Mitigation Measures: For our analysis, we will not only rely on historical and statistical data but also take into account current analyses and forecasts that are created in terms of the influence of Covid-19 on the target market and globally.



Figure 1: Business Model Canvas

D-Ject USP & Future steps



Basic analytics

Data processing of the measured sensors data for:

- 3D Trajectory of the injection (USP e-Needle)
 - Angle and depth of the injection
 - Point of contact and area
- Orientation

Basic training VR simulator

Based on research and studies related to injections techniques with motion capture to know how to inject using:

- Best injection technique and best practice (USP VR Simulator)
 - Realistic environment (USP VR Simulator)

- Characterization of the tool depending on the training required

Advanced training VR simulator

Based on research and studies related to injections techniques with motion capture to know how to inject using:

Different tools, type of needles, list of injections...

D-Ject Market Size (TAM-SAM-SOM Approach)

			Gr	aduates in faculties	of medicine				
		Addressed on year	TAM*	% over world	% over continent	SAM	SAM**	SOM	SOM***
World			264.562.644						
Europe			60.032.476	22,69%					
	Scandinavia+Turkey	2022	18.697.416	7,07%	31,15%	2.243.690	12%	336.553	15%
	Rest of Europe	2023	41.335.060	15,62%	68,85%	2.066.753	5%	103.338	5%
America			71.249.790	26,93%					
	US	2024	24.472.778	9,25%	34,35%	2.508.460	10%	100.338	4%
	Rest of america****	2026	32.683.417	12,35%	45,87%	1.961.005	%9	39.220	2%
Asia			84.517.798	31,95%					
	Japan	2027	4.805.150	1,82%	5, 69%	480.515	10%	28.831	6%
TOTAL			602.356.529			9.260.423		608.281	
				Hospitals					
		Addressed on year	TAM*	% over total	% over continent	SAM	SAM**	SOM	SOM***
World			327.008						
Europe			156.953	48,0					
	Scandinavia+Turkey	2022	37.934	11,6	24,2	17.070	45%	2.390	14%
	Rest of Europe	2023	119.019	36,4	75,8	29.755	25%	2.975	10%
America			73.791	22,6					
	US	2024	9.000	2,8	12,2	1.800	20%	252	14%
	Rest of america	2025	64.791	19,8	87,8	4.535	7%	454	10%
Asia			20.463	6,3					
	Japan	2027	2.000	0,6	9,8	300	15%	42	14%
TOTAL			810.959			53.460		6.113	
TANA T	tal Addressable Market) = https://data ceed	m/sord+leod/mo	td atomptor pt					

*TAM (Total Addressable Market) = https://data.oecd.org/healthres/medical-graduates.htm
**SAM (Serviceable Available market) = % of the total addressable market (TAM) that can actually be reached
***SOM (Serviceable Obtainable market) = % of the SAM that is realistically within reach considering resources and competitors
**** Brazil+Canada+Colombia+ Chile+Argentina+Mexico



NEGENTRA Software, Information Technologies, Education, Consultancy, Research & Development, Industry and Trade Ltd.: D-Ject: A Realistic Virtual Reality Device with Haptic Feedback for Risk-Free No-Touch Medical Injection Training (D-Ject)

To be submitted as a project proposal within the XR4ALL 2nd Open Call

I, the undersigned, confirm on behalf of my organisation, Funfox Software LLC, our general support and cooperation for the D-Ject project that will be developed by Negentra during the dedicated XR4ALL 2nd Open Call

Negentra Software, Information Technologies, Education, Consultancy, Research & Development, Industry and Trade Ltd addresses commercial and technical problems associated with D-Ject: A Realistic Virtual Reality Device with Haptic Feedback for Risk-Free No-Touch Medical Injection Training in Europe and worldwide. It aims to bring to the market a novel innovation.

We believe that the D-Ject project is in line with our goals and strategies. I hereby confirm that Funfox Software LLC will supervise the please, insert the task of the supporting sound engineering that will be implemented by the company during the envisaged Phase2 project. We fully support this initiative and encourage XR4ALL to fund this project and wish every success to Negentra Software for the accomplishment of the proposed work.

22/11/2020 Serdar ÇELİK

FUNFOX YAZILIM BILIŞİM ARGE SAN. TİC. L'TD. ŞTİ. 'enişehir Mah. Kardeşler Çad. Teknokent Sitesi No : 5/117 SİVAS / Tel 0505 223 59 70 Site V.D.: 388 1075 109 - Tic. Sicil No : 16026 Mersis No : 0388107510900001

NEGENTRA Software, Information Technologies, Education, Consultancy, Research & Development, Industry and Trade Ltd.: D-Ject: A Realistic Virtual Reality Device with Haptic Feedback for Risk-Free No-Touch Medical Injection Training (D-Ject)

To be submitted as a project proposal within the XR4ALL 2nd Open Call

I, the undersigned, confirm on behalf of my organisation, Istanbul University, Faculty of Dentistry, our general support and cooperation for the D-Ject project that will be developed by Negentra during the dedicated XR4ALL 2nd Open Call

Negentra Software, Information Technologies, Education, Consultancy, Research & Development, Industry and Trade Ltd addresses commercial and technical problems associated with D-Ject: A Realistic Virtual Reality Device with Haptic Feedback for Risk-Free No-Touch Medical Injection Training in Europe and worldwide. It aims to bring to the market a novel innovation.

We believe that the D-Ject project is in line with our education goals and strategies. I hereby confirm that Istanbul University, Faculty of Dentistry, fully support this initiative and encourage XR4ALL to fund this project and wish every success to Negentra Software for the accomplishment of the proposed work.

(wei 18.12.2020 Volkan ARISAN

NEGENTRA Software, Information Technologies, Education, Consultancy, Research & Development, Industry and Trade Ltd.: D-Ject: A Realistic Virtual Reality Device with Haptic Feedback for Risk-Free No-Touch Medical Injection Training (D-Ject)

To be submitted as a project proposal within the XR4ALL 2nd Open Call

I, the undersigned, confirm on behalf of my organisation, Sensoryx AG, our general support and cooperation for the D-Ject project that will be developed by Negentra during the dedicated XR4ALL 2nd Open Call.

Negentra Software, Information Technologies, Education, Consultancy, Research & Development, Industry and Trade Ltd addresses commercial and technical problems associated with D-Ject: A Realistic Virtual Reality Device with Haptic Feedback for Risk-Free No-Touch Medical Injection Training in Europe and worldwide. It aims to bring to the market a novel innovation.

We believe that the D-Ject project is in line with our goals and strategies. I hereby confirm that Sensoryx AG will contribute with the commercial supply of tracking sensors for virtual reality devices during the envisaged Phase2 project. We fully support this initiative and encourage XR4ALL to fund this project and wish every success to Negentra Software for the accomplishment of the proposed work.

In no event will Sensoryx AG or its affiliates be liable for any direct, indirect, punitive, special, incidental or consequential damages in connection with or arising out of its voluntary participation in the Consortium (including loss of business, revenue, profits, use, data or other economic advantage).

Yours Sincerely,

1. plated

Mark Moutarde Head of Sales Sensoryx AG 07/12/2020



INSTITUTE OF TECHNOLOGY

04.12.2020

Letter of Intent for Support:

D-Ject: A Realistic Virtual Reality Device with Haptic Feedback for Risk-Free No-Touch Medical Injection Training

To be submitted as a project proposal within the XR4ALL 2nd Open Call

I, Prof. Gholamreza Anbarjafari, head of iCV Lab, confirm our full support of the XR4ALL 2nd Open Call Project "D-Ject: A Realistic Virtual Reality Device with Haptic Feedback for Risk-Free No-Touch Medical Injection Training" to be submitted on the 18th of December 2020.

D-Ject offers an innovative and disruptive Virtual Reality Device for medical education. It is a realistic Virtual Reality Device with Haptic Feedback for Risk-Free No-Touch Medical Injection Training in Europe and Worldwide.

We hereby confirm that iCV Lab will consult and supervise all the activities determined in the work plan of the project that will be coordinated by Negentra. Our involvement would be on recommendation and suggestion basis and Negentra will be fully responsible for all implementations.

We fully support this initiative and wish every success to Negentra for the accomplishment of the proposed work.

Yours Sincerely

Prof. Dr. Gholamreza Anbarjafari

Head of iCV Research Lab, University of Tartu, Narva mnt 18, Tartu 51009, Estonia Tel: +372 737 4855 Email: <u>shb@icv.tuit.ut.ee</u>

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NEGENTRA Software, Information Technologies, Education, Consultancy, Research & Development, Industry and Trade Ltd.: D-Ject: A Realistic Virtual Reality Device with Haptic Feedback for Risk-Free No-Touch Medical Injection Training (D-Ject)

To be submitted as a project proposal within the XR4ALL 2nd Open Call

I, the undersigned, confirm on behalf of my organisation, Game Developers Association of Turkey, our general support and cooperation for the D-Ject project that will be developed by Negentra during the dedicated XR4ALL 2nd Open Call

Negentra Software, Information Technologies, Education, Consultancy, Research & Development, Industry and Trade Ltd addresses commercial and technical problems associated with D-Ject: A Realistic Virtual Reality Device with Haptic Feedback for Risk-Free No-Touch Medical Injection Training in Europe and worldwide. It aims to bring to the market a novel innovation.

We believe that the D-Ject project is in line with our goals and strategies. I hereby confirm that Game Developers Association of Turkey, fully support this initiative and encourage XR4ALL to fund this project and wish every success to Negentra Software for the accomplishment of the proposed work.

22/11/2020 Ali Erkin Chairman of the Board

NEGENTRA Software, Information Technologies, Education, Consultancy, Research & Development, Industry and Trade Ltd.: D-Ject: A Realistic Virtual Reality Device with Haptic Feedback for Risk-Free No-Touch Medical Injection Training (D-Ject)

To be submitted as a project proposal within the XR4ALL 2nd Open Call

I, the undersigned, confirm on behalf of my organisation, Tundra Labs, LLC, our general support and cooperation for the D-Ject project that will be developed by Negentra during the dedicated XR4ALL 2nd Open Call

Negentra Software, Information Technologies, Education, Consultancy, Research & Development, Industry and Trade Ltd addresses commercial and technical problems associated with D-Ject: A Realistic Virtual Reality Device with Haptic Feedback for Risk-Free No-Touch Medical Injection Training in Europe and worldwide. It aims to bring to the market a novel innovation.

We believe that the D-Ject project is in line with our goals and strategies. I hereby confirm that Tundra Labs will contribute with the supply of tracking sensors for virtual reality device during the envisaged Phase2 project. We fully support this initiative and encourage XR4ALL to fund this project and wish every success to Negentra Software for the accomplishment of the proposed work.

In no event will Tundra Labs or its Affiliates be liable for any direct, indirect, punitive, special, incidental or consequential damages in connection with or arising out of its voluntary participation in the Consortium (including loss of business, revenue, profits, use, data or other economic advantage).

30/11/2020 Luke Beno - CEO

NEGENTRA Software, Information Technologies, Education, Consultancy, Research & Development, Industry and Trade Ltd.: D-Ject: A Realistic Virtual Reality Device with Haptic Feedback for Risk-Free No-Touch Medical Injection Training (D-Ject)

To be submitted as a project proposal within the XR4ALL 2nd Open Call

I, the undersigned, confirm on behalf of my company, Viveka, our general support and cooperation for the D-Ject project that will be developed by Negentra during the dedicated XR4ALL 2nd Open Call

Negentra Software, Information Technologies, Education, Consultancy, Research & Development, Industry and Trade Ltd addresses commercial and technical problems associated with D-Ject: A Realistic Virtual Reality Device with Haptic Feedback for Risk-Free No-Touch Medical Injection Training in Europe and worldwide. It aims to bring to the market a novel innovation.

We believe that the D-Ject project is in line with our goals and strategies. I hereby confirm that Viveka, fully support this initiative and encourage XR4ALL to fund this project and wish every success to Negentra Software for the accomplishment of the proposed work.

23/11/2020 Emin Okutan Co-Founder Viveka