# User Involvement in R&D at Novo Nordisk

Diabetes Treatment Development



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## **Abstract**

Globalization is a strong factor of change and a major challenge for organizations. With dynamic changes occurring on the market, competition becomes fierce. Therefore, companies ought to search for new ways to compete.

Nowadays, organizational resources become key strategic factors for retaining market share. The best resource of Novo Nordisk is innovation reinforced by its Research and Development department. However, with the rapid growth of high technology, the company has to go an extra mile to maintain its leadership in the world's diabetes treatment production.

Using User-Driven Innovation as a unique strategy in R&D, we explain how Novo Nordisk has applied the concept in practice. Whether it is by using patients' ideas to innovate or improve products, or as a strategy for competition. As our findings show, more value is created and cocreated by involving patients in the company. Opening to a dialogue based on mutual trust, as well as formulating guidelines of practice, assists in effective cooperation.

On the example of Novo Nordisk, we explain how user involvement can help understand needs and wants of patients through interaction and knowledge-sharing across the organization's boundaries.

# Keywords: User-Driven Innovation, UDI, user involvement, value creation, value cocreation, Knowledge, Digitalization and Patients

# **Contents**

Abstract	1
1. Introduction	4
1.1 User-Driven Innovation	4
1.2 Problem Statement	7
1.3 Research questions	7
1.4 Justification	8
1.5 Case Study: Novo Nordisk	9
1.5 A. The first insulin	10
1.5 B. Human insulin	12
1.6. Mini Case on User involvement. EUPATI	13
2. Literature Review	16
2.1 User Driven Innovation	17
2.2 Value Creation	19
2.3 SD-logic Co-creation and Co-destruction of value	22
2.4 Knowledge as part of value creation	24
2.5 Digitalization as a means of value creation	25
2.6 Identities of interviewees and co-production of information	26
3. Methodology	27
3.1 Introduction	27
3.2 Research philosophy and paradigms	28
3.3 Role of the researchers	29
3.4 Methods	30
3.4.1 How the qualitative interviews were conducted	30
3.4.2 Choosing appropriate participants for the research	30

3.4.3 Preparing a research protocol	30
3.4.4 Devising useful interview questions intended to capture the data required	31
3.4.5 Creation and exhibition of affinity with the participants and attentive listening	31
3.4.6 Available methods and alternatives	31
3.5 Justification of method	32
3.6 Sample size	32
3.7 Semi-structured interview approach	33
4. Analysis	34
4.1 Introduction	34
4.2 User Involvement	35
4.3 Patient Involvement	38
4.3.1 Pharmaceutical industry-led medicines R&D	40
Figure 6. Pharmaceutical industry-led medicines R&D Warner et al. (2018)	40
4.4.2 Ethics committees	42
4.5.3 Regulatory authorities	44
4.5.4 Health technology assessment (HTA)	46
4.6 Value creation	48
Value to patients and professionals including carers	48
Value to Novo Nordisk	50
4.7 Digitalization to create value	53
Digitalization at Novo Nordisk	53
Digitalization benefits for patients	55
Tandem T: slim X	56
4.8 Knowledge for value creation	58
Conclusions	63
Bibliography	67
Appendix	77

Interview guide.	77
Appendix 1 2 3 4 5 attachements	77

## 1. Introduction

## 1.1 User-Driven Innovation

The growth in globalization, coupled with the rapid advancement in technology, has necessitated organizations' constant strive to not only be relevant in the market but also acquire new segments of the market or at least, maintain their niche. This has caused organizations to invest huge sums of money and resources in Research and Development (R&D) in order to facilitate innovation with the aim of satisfying their customers or perhaps, acquiring new customers (Karadal & Sayging, 2011).

Most companies today are in competition producing or marketing the same or similar products or are under pressure to meet the needs of their consumers. Organization use innovation as strategy to reach the demands and preferences of consumers. Innovation is vital to economic development and sustainable growth. According to Joseph Schumpeter, also known as the "prophet of innovation", innovation is an activity which leads to producing a new service or product (Ramadani & Gerguri, 2010). Innovation is very important to businesses, as it secures competitive advantage and leads to improved performance (Mohd Zawawi *et al.*, 2016)

The discipline of innovation is extensive and it's concept keeps evolving. With the aid of information and communication technologies, the value addition process has changed the balance of power among firms and consumers (Wise & Casper, 2008; Tacer, Ruzzier, & Nagy, 2018). Organizations can no longer depend exclusively on operational effectiveness or technological superiority to create a competitive advantage. Involving consumers or users in the innovation process is now key in defining and delivering unique experiences (ibid). The concept of innovation comes with complexities due to ever-changing technology. Scholars such as Maren Hartmann has observed its three main classifications (Hartmann, 2014). In her paper "Back to the root: What is user-driven innovation?", she classified innovation into price-driven, research-driven, and user-driven (ibid).

In recent times, one of the newest ideas conceived in the approaches to innovation is User-Driven Innovation (UDI). The UDI idea, which started to gain traction in the academic circles and later transcended into the business environment in 2005, stands on the conviction that, purchasers (users) have an expanding effect on the business offer accessible (Szymańska, 2017). Undoubtedly, they partake in the production of goods and services that they purchase. UDI can be explained as the way of encouraging clients' knowledge to develop new products services. This process depends on a veritable comprehension of users' needs and deliberately connecting with users' during the development process (ibid). The consumer is now the focus. Which implies that, "instead of selling what we produce, we produce what sells" (Hans Stråberg in: Rosted, 2005). The consumer will always be the center of convergence when new items and ideas are produced (ibid).

User-driven innovation is portrayed by the systematic and logical mapping of client needs, together with organizations' ability to access potential to transform relevant ideas into innovation. The growing success in the Western world, has increased buyer requests for product value and experiences, which has prompted a developing enthusiasm for user-driven innovation (ibid).

The conception of new ideas does not always emerge from formal industrial research development. Consumers have brilliant and innovative ideas that result in the production of new and improved goods and services. They know what best suits their needs, and therefore they are in a better position to design, build and distribute their own solutions. User-driven innovation could take the form of feedback and support or making a new product (NESTA, 2008).

Including customers in the innovation procedure, involves a host of new concerns, ideas, and managerial decisions. Changing from more established models of no or low client contribution, expects regard for the distinctive kinds of client development, authoritative mission and hierarchical structure. Smart firms have started to tap into the knowledge of their "lead clients" through customer workshops for information that can enable the firm to make advancement in production of new products and enhancement of the existing ones (Desouza et al., 2008). Research into the process of innovation has revealed that numerous modern services and products are results of the incorporation of the users' emerging ideas which are continuously implemented in product and service improvement (Franke & Shah, 2003).

User-driven innovation is making strides in Nordic nations (Bisgaard & Høgenhaven, 2010). Most Danish organizations rarely use advanced scientific and ethnographic analysis tools. Instead, much attention is given to User-Driven Innovation which can be attributed to a firm customer focus and

a broad utilization of customer reviews (Rosted, 2005). Among other organizations, Novo Nordisk, is a leading health care facility in Denmark. The company recognizes that involving customers in the innovation process is vital because the customer are the ones living their lives with the diseases. Therefore, involving them in the innovation process aids in developing the most ideal new prescriptions (Novo Nordisk, n.d-a.).

Novo Nordisk's Bioethics Policy implies that it discovers, develops and produces biological medicines with respect for people, animals, and the environment (Novo Nordisk, n.d-b.). This means that they operate by high ethical global standards in research involving people, animals, human material and gene technology (ibid).

Novo Nordisk invests in and markets several products for the treatment of diabetes (ibid). Diabetes mellitus (DM) is a glucose metabolism disease characterized by chronic hyperglycemia caused as a result of defects in insulin secretion, insulin activity, or both (Gao et al., 2017). Diabetes is a major concern for human health and according to the World Health Organization (2010) "the overall risk of dying among people with diabetes is at least double the risk of their peers without diabetes". Type 1 diabetes is as a result of inadequacy in insulin-induced by the failure of secretion by the pancreas (Gao et al., 2017). On the other hand, type 2 diabetes is characterized by insulin resistance and relative insulin insufficiency.

Insulin - the hormone that regulates blood sugar, is the most prominent and anchor treatment for patients with type 1 diabetes. If in patients with type 2 diabetes, blood glucose levels cannot be maintained by controlled diet, weight reduction, exercise, or oral medication, insulin is used (Sheeja et al., 2010; Pathak & Singh, 2015).

Stephen Charles Langford Gough, the Global Chief Medical Officer at Novo Nordisk states that, "improving the lives of people and reducing the burden of diseases require putting the patient at the center of everything that we do. At Novo Nordisk, patients are involved not only in clinical trials but also in the design of our research programmes." (novonordisk.com, n.d.). Thanks to their unique insights, Novo Nordisk patients involvement helps to understand the effects of serious chronic diseases on patients everyday lives (ibid). Due to their commitment to corporate responsibility, Novo Nordisk implement public views and interests. (Novo Nordisk, n.d.-b). Customers are a significant part of innovation, especially in healthcare industry. 90 percent of organizations concerned with health care are involving customers in the industry (Rosted, 2005).

#### 1.2 Problem Statement

What is User-Driven Innovation? How organizations use their core resources as a strategy and how pharmaceuticals involve users in Research and Development (R&D)?

# 1.3 Research questions

- 1. How has Novo Nordisk used the concept of user-involvement in R&D?
- 2. How has Novo Nordisk implemented the concept of user-involvement for value creation?
- 3. How has Novo Nordisk exploited the potential of the user-involvement in R&D?

The conventional shift towards user-driven innovation strategies in the information and communication technologies, has caused organizations to make their customers the focus of their innovation process in an increasingly efficient manner (Moor et al., 2010). User-driven innovation produces new and effective ideas, as well as, products and services for organizations. That is done through cooperation with the customers and incorporating them in the innovation process by drawing on their needs, desires and perhaps their issues. This concept has been adopted by several organizations regardless of their industry (Bisgaard & Høgenhaven, 2010).

Healthcare industry is characterized by a unique set of technical skills. Leading Danish organizations and associations are centered on working efficiently together with their customers in their innovation processes. They have included new techniques and tools, such as, ethnographic research, to reveal the clients' unacknowledged needs (Wise & Casper, 2008). Their focus is on good salesmanship rather than competing against other companies in the area of technology and price. This requires organizations to be very good at recognizing market opportunities and manufacturing the most innovative and easy to use products, services, and solutions (ibid). Patients have expectations of high-quality service delivery from healthcare organizations (Jæger, 2010). People living with chronic diseases are considered to be experts because they have the experience of managing the disease in their daily lives.

An average diabetic patient will need to take insulin injections approximately 60,000 times throughout their life (Pathak & Singh, 2015). Therefore, there is a need to involve patients directly in the diabetes treatment production process all the way to its administration to ensure its effectiveness.

Organizational innovations happen in the process of production and the improvement of product and service that can result in economic returns for them (Rosted, 2005). However, organizations do not always get successful innovations resulting in the increment of their products and services (Bisgaard & Høgenhaven, 2010). Thus, if innovation investments are to yield desired outcomes, they must consider consumer needs. That is, however, becoming increasingly challenging. With the ascent of the Internet and progressive worldwide markets, customers are met with seemingly boundless choices. We no longer purchase what we see, but instead search out for what we want to purchase. Complex consumer demand is an imperative driver of innovation. To maintain a competitive edge, more attention must be given to addressing consumers' needs. Not just what is stated and expressed in market research, but instead, the consumer needs which can be uncovered through analytical methods, and by the consumers themselves. Thus, user-driven innovation is ascertaining an increasingly deliberate approach to understand and create solutions that meet consumers' needs (Wise, 2006).

User-driven innovation requires substantial resources for mapping, analyzing and assessing customer needs, therefore, the need to understand how Novo Nordisk uses this concept in diabetes development.

## 1.4 Justification

Novo Nordisk has been successful in the production of treatments for diabetes by the combination of its active participation in debates and open communication with the public and the use of gene technology for research and production. Based on 25 years of risk assessments and safety records, no damage to human health or the environment has ever been recorded (Novo Nordisk, n.d.-b). At the same time, millions of people have been treated for serious diseases (ibid). We believe that User-Driven Innovation has a significant effect on Novo Nordisk and has enhanced the organization's innovation abilities and product performance (Tacer & Ruzzier, 2015).

Granting users, the opportunity to innovate, makes it possible for them to create something that is not available in the market that suits their needs and wants. In a Meta-analysis of market-

segmentation studies by Franke and Reisinger (2003, in: Von Hippel, 2005), the authors suggest that users' needs for products are highly heterogeneous in many fields. At the point when customers' needs are heterogeneous, technique of "a few of sizes fit all" will leave numerous customers disappointed with the business product on offer and most likely leave a few customers truly disappointed.

According to Desouza *et al.* (2008), transitioning from older models of no or low customer involvement to a competitive marketplace where organizations are changing their innovation strategies from "innovating for customers" to "innovating with customers". Involving these customers in a process of "knowledge co-creation" enables them to become increasingly connected with the organizations and other customers become partners in product/service innovation.

Studies show that involving users in the innovation process leads to cost reduction and higher degrees of efficiency (Archakova & Mazur, 2011).

# 1.5 Case Study: Novo Nordisk

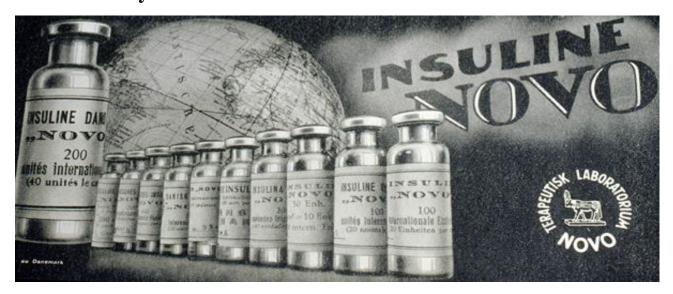


Figure 1 First insulin, (Novo Nordisk, 2011).

Novo Nordisk (2011) states that over 425 million people in the world live with diabetes today. Which means that approximately 1 in 10 of the world's adult population is likely to be affected by the disease or someone close to them is affected by it. With better diagnosis, diabetes is treatable and people with the disease can expect to live a full, healthy and active life with better management.

Novo Nordisk began the journey to defeat diabetes type 1 and 2 in 1923 (ibid). Insulin being one of Novo Nordisk biggest achievements, has continued to go through R&D over and over again to make life manageable for people struggling with the disease.

Insulin is a treatment for diabetes, mainly type 1, and it has gone through major developments to suit the patients since it's discovery in 1920s (ibid).

What is diabetes, then? It is a serious chronic disease resulted by the body not producing or using insulin a hormone that moves glucose, which causes the body to have high level of blood glucose. There are 3 types of diabetes: type 1, type 2 and gestational diabetes (ibid).

This thesis is interested in developing an understanding how Novo Nordisk involve patients in R&D and how value is co-created.

Novo Nordisk is a global healthcare company with over 85 years of innovation and leadership in diabetes care (ibid). The company is also a leader in hemophilia care, growth hormone therapy and hormone replacement therapy. Novo Nordisk headquarters in Denmark employs more than 30,000 employees in 76 countries and markets its products in 179 countries.

Novo Nordisk is a merger of two small Danish firms established in Copenhagen in the 1920s – Nordisk Insulinlaboratorium (NI) and Novo Terapeutisk Laboratorium (NTL). Nordisk Insulinlaboratorium was founded in late 1922 by a couple named August and Marie Krogh. Marie Krogh had type 2 diabetes and she was interested in the treatment of insulin – a hormone that was discovered by two Canadian researchers Banting & Best in 1921 (ibid). In fact, the Canadian Institute in Toronto is where the first insulin was extracted and produced.

NI and NTL competed fiercely against each other as a result of them being the two best enterprises in their field. The two establishments decided then, to enter into a merger in 1989, creating the world's largest biotechnology group Novo Nordisk that has continued to grow rapidly ever since (ibid).

## 1.5 A. The first insulin

The first successful experiments to extract a small quantity of insulin from a bovine pancreas in Denmark, took place towards the end 1922 (Krogh, 1923, in: Novo Nordisk, 2011). In 1923, the first patients were treated with insulin manufactured by Krogh and Hagedorn (the two companies). Although the treatment was not consistently successful, it improved the lives of the patients

without a doubt (Hagedorn, 1923, in: Novo Nordisk, 2011). A year later, Novo Terapeutisk Laboratorium managed to produce a better and stable insulin called Insulin Novo. The company also managed to design a special syringe called the Novo Syringe to help patients inject themselves with a precise dose of insulin (ibid).

Novo Nordisk (2011) stated that in the early 1930s, researchers in insulin realized that the effect of the current insulin products was short-lived and came with serious side effects on patients. It also implied the need of many injections in a day. Therefore, Nordisk and Novo dedicated their research to finding a better and longer-acting type of insulin. It did prove successful in 1935, however, it failed due to its side effects. The advancement of R&D continued, and in 1936 there was improved development of insulin with long-lasting effects that needed adding a protein called protamine from the milt of river trout. This protein became the most important advancement in "the treatment of diabetes since the discovery of insulin in 1921" (ibid).

Even though the new product was good, there was a downside that came with it. Patients were to add a neutralizing liquid before using the insulin, making it difficult to manage. This was later resolved by two Canadian researchers - D. A. Scott & A. M. Fisher, who developed a long-acting product – zinc-protamine-insulin (ZPI) – that only required to be shaken before use (ibid). "In 1938, Novo founded Hvidøre Diabetes Sanatorium, the name of which was changed to Hvidøre Hospital in 1949" (ibid). Subsequently, in 1944 an alternative to ZPI was developed, the action profile of which was not optima (ibid)l. In 1946, two of its researchers - C. Krayenbühl and Th. Rosenberg, succeeded in producing a better insulin crystalline protamine which had rapid-acting insulin without any loss or change in effect of either product(ibid). The insulin was launched on the US market in 1950 under the name Neutral Protamine Hagedorn (NPH) and soon became the Western world's most used long-acting insulin. The research team was also experimenting with development of a better insulin (ibid). In 1953, the insulin Lente® product was developed and dominated the market for many years covering nearly a third of the world's insulin consumption. Although this product was referred as the best one since 1920, US medical research in 1960 showed that all people with diabetes formed antibodies against the insulin, weakening the effects of the treatment, Thus, the patients needed increasingly larger doses to keep their disease under control (ibid). In 1973, the research on antibody reactions led to development of insulin Monocomponent insulin (MC insulin). The innovation continued to develop with improved

purification methods and, in 1974, the company launched an improved, highly purified porcine insulin (ibid).

## 1.5 B. Human insulin



Figure 2 Humalog - the first human insulin, Novo Nordisk, 2011.

After the success of highly purified insulin, in the 1970s the companies continued their research with the aim of producing human insulin that was the same as the insulin produced by the body. In 1982 Novo become the first company in the world to convert porcine insulin into human insulin to replace a single amino acid in the porcine insulin molecule (ibid). In 1987, Novo produced human insulin based on genetically engineered yeast cells and stopped depending on animal pancreases. This meant that Novo could produce almost unlimited quantities of insulin leading to market growth.

Nordisk Infuser and NovoPen® were introduced in the 1983. This was because in the 1980s, doctors became aware that long-term diabetic complications such as kidney failure and blindness could be delayed or avoided with better control of patients' blood sugar (ibid). In 1983, Nordisk marketed an insulin pump called Nordisk Infuser. The pump constantly released small quantities of insulin to the body of the patient giving them most normal blood sugar level the body needed (ibid). The elegant NovoPen® device provided the patients with simple means of injecting themselves with exactly the right dose of insulin several times a day. Likewise, the patients were able to control their blood sugars levels, as well as manage the treatment with less risk of developing the unpleasant long-term diabetic complications (ibid).

Novo produced the world's first disposable insulin syringe NovoLet® that was prefilled, making it the easiest and the most flexible insulin injection to use, with its high dosage accuracy.

Novo Nordisk (NN) has continued to be the strongest leader in diabetes treatment production globally. To the company diabetes is more than just insulin. NN develops other diabetes treatments as well. Innovation has been the strongest resource for the company, and it continues to invest into R&D.

Based on the company's press release in 2018, NN plans to restructure the organization of R&D in order to accelerate the diversification and expansion of its pipeline and to enhance investment in transformational biological and technological innovation (Novo Nordisk, 2018).

### 1.6. Mini Case on User involvement. EUPATI

According to Geissler (2017), the European Patients' Academy on Therapeutic Innovation is a pan-European NGO project, implemented "as a public-private partnership by a collaborative multistakeholder consortium from the pharmaceutical industry, academia, not-for-profit and patient organizations" (ibid). It was funded in 2012 within the Innovative Medicines Initiative (IMI). EUPATI was formed to empower patients with information about their disease. It is based on the conviction that involving patients in research is beneficial to the medicine's development process (ibid). By considering patients' priorities and viewpoints, it potentially contributes toward permanent improvements in their treatments. Additionally, patient involvement in R&D can increase the effectiveness and safety of new treatments, hence the increase in public support for medical research (ibid). The academy aims to change the way patients and public understand the medicines development process and ensure the effect of their involvement. EUPATI objectives are formulated by the European Patients' Forum (EPF), patients' organizations, academic groups, NGOs and pharmaceutical companies (ibid). Most of the objectives are about empowering "patient experts" and advocates with a deeper understanding on how to work effectively with relevant authorities, healthcare professionals and industry, in order to make an impact on the process of medicines development for the benefit of patients. EUPATI emphasizes that patient involvement is all process and work towards the following objectives:

1. "To develop and disseminate accessible, well-structured, comprehensive, scientifically reliable and user-friendly educational material for patients on the processes of medicines R&D, especially on end-to-end R&D processes, i.e. non-clinical R&D, clinical trials,

- personalized medicine, efficacy and safety assessment, risk benefit assessment, health economics, HTA and patient involvement in these processes,
- 2. To increase the capacity of "patient experts" and well-informed patients in patient organizations so to be effective advocates and advisors in medicines research and development,
- 3. To empower patients to provide appropriate patient-relevant advice and insight to industry, academia, authorities and ethics committees is not only concerned with the practical training of patient experts and the dissemination of unbiased, objective information about the systems and processes of research and development" (ibid).

The academy provides its educational materials in 7 languages (English, German, Spanish, Polish, French, Russian and Italian), which serve 12 European countries. This is to make sure the quality and facts are accurate, neutral, accessible and readable.

EUPATI believes that it has established and produced credible content full of knowledge through their actors. The academy is for public use; however, one must meet certain criteria before joining or getting involved in the activities (ibid). Moreover, the academic material can be used for NGO purposes or for recruitment of suitable patients for clinical trials.

The four phases of clinical trials will be discussed later on.



Figure 3 Phases of Clinical Development, EUPATI, nd.



Figure 4. EUPATI partners, (www.eupati.eu).

## 2. Literature Review

In this section, literature review about User-Driven Innovation (UDI) and user involvement is presented. The literature review is an overview of the research on the UDI and the path of innovation that creates value using UDI and user involvement.

To gain better understanding of the research on UDI, we performed context research using major library databases by inserting "User-Driven Innovation" and "user involvement" as search criteria in the title, keywords or abstracts view. We also conducted a literature review on chosen theories to understand how Novo Nordisk uses UDI to its advantage

While there exist different types of innovation, the choice of the User-Driven kind is based on our thesis problem formulation. We wish to understand how involving the user can play the key role in innovation and in, our case, diabetes treatment. Moreover, we wish to find out how to conceptualize the UDI using other theories to study Novo Nordisk Research and Development (R&D) process.

Ackerman, *et al.* (1999) state that technological innovation, engineering, marketing, management and economics innovation stipulate unique drive to what is regarded as innovation. This literature review will provide an overall perspective on innovation studies in relation to technological innovation. The best interactive process influenced by prospective market or service opportunity for a technology-based invention.

Boell and Cecez-Kecmanovic (2010) state that literature review is built using different methods while researching a topic such as search operators and field search. The writer depends on search strategies to be more focused on chosen fundamental literature, as well as additional supplementary publications. The identified theories assist in obtaining relevant literature in different search genres. It should be noted that literature review is a hermeneutic process and it is evident that there is no absolute understanding of the literature (ibid). In essence, constant reinterpretation guides to profound and more inclusive understandings of relevant publications. Furthermore, the social science and humanities literature reviews are better understood as ongoing processes that increase better understanding of the research area and the research problem (ibid).

## 2.1 User Driven Innovation

Increasingly more intense discussions about integrating users into the process of innovation are emerging. Tacer and Ruzzier (2015) describe how some publications and practices recognize the beneficial impact of involving users in the process of innovation. The authors underline that a company can improve its innovation capabilities as well as product performance using UDI. Likewise, some literature argues that integrating users into the innovation process brings the potential of hindering a company's innovation process. In some cases, it leads to simple incremental innovations (ibid). Nevertheless, UDI is a promising research path that several researchers have written about regarding innovation that has contributed towards the development of the theory and the concept ideas of UDI.

Trott, Duin and Hartmann (2013), since the 1950s the theory of technology drive of innovation has been challenged at the centre of science and innovation policy. Indicating that research exploring the role of users as innovators by different groups of academic fields is becoming increasingly extensive. This research involves a variety of theoretical perspectives, such as social exchange theories and economic motivation theories for information sharing (ibid). The UDI support has grown in the past 30 years with little significant or critical assessment. This is compared with the literature on innovation of the last 35 years on products such as cellphones, personal computers and the Internet, where it suggests that user involvement was quite minimal if any (ibid).

Rocheska *et al.* (2014) explain that in general, the development of society is driven by innovation. Yet, the innovation debate only became widely spread in the second half of the 20th century, when powers of change in economic or cultural context were deepened globally. Furthermore, the authors outline that in modern markets, innovation is the driving influence for companies' achievements and competitiveness (ibid). Stating that companies can no longer deny the relevance of innovation and its contribution to boosting efficiency. An organization can create more competitive platforms in the global market, as well as become a leader in global innovation. Given the fact that the environment is dynamic, a company's success is decided, or directed, by interactions which it is built upon, its competitors, institutions and its users, form strategies for new idea creation and promotion of technological change.

In current global markets, the nature of interacting with innovation and absorption of external knowledge is becoming progressively important for organizations to refine their innovation feat (ibid)

De Magdala Pinto and Pedruzzi Fonseca (2013) mention that, "the idea of users' direct involvement in the innovation process was first proposed by William Mitchell, to whom the proposition of Living Labs as research and development (R&D) methodologies in which the final users were considered to be central is attributed". The researcher Eric von Hippel, on the other hand, explored the kind of innovation that is endorsed by users, particularly lead-users, who focus on the limitations of the product or service provided by the market (Von Hippel, 2005). He argues, that this kind of innovation is user innovation and it follows the open innovation concept (ibid). Likewise, the author states that the open innovation concept (which is the main focus of many organizations) has been acknowledged by both the academic community and users to be very valuable in innovation (ibid).

The ideas of users driving the design of a product or service and its value towards the process of innovation processes only become fierce in Europe at the beginning of the 20th century. The platform of Living Labs was developed by the Computer Supported Cooperative Working research community in 2005 as venture exploring a firm mentioned ideas (de Magdala Pinto & Pedruzzi Fonseca, 2013).

Liedtke *et al.* (2012) express that Living Labs highlight the remarks made by von Hippel (in: Hippel, 2005) stating that involving end users actively in the innovation life cycle of a product or service is a strong strategy for competitiveness in an organization that deem innovation as a its core resource.

What are Living Labs?

Living Labs are open innovation platforms shared by different stakeholders such as organizations, end users, software companies, IT research organizations, and public administrations. Such a *cluster* allows members to share innovation interests and present specific needs. It provides physical and virtual environments for open and user-driven innovation developments (Garcia et al. 2008).

These structures are to facilitate co-design, provide *testbeds*, and induce collaboration. Living labs serve also as a knowledge management tool that supports interaction between stakeholders that usually involve the user communities, organization and researchers. The focus of such labs is to

manage incoming ideas for new products and services which are directly based on the needs and desires of end-users. Moreover, the labs serve to promote the development of these ideas by providing the tools and technological solutions necessary to launch the potential products and services.

Living labs state that their concept is rapidly growing in many companies. The approach to involve users in the development and improvement of products and services life cycle has been successful especially in software companies (ibid). However, Chesbrough and Euchner (2011) argue that, living labs are complex experiments that need not only physical facilities but also attentive development of essential relationships and networks to be a success.

Rocheska *et al.* (2014) argue that customers role in innovation of organizations goes further than the innovation itself. Organizations aim to design products and service that meets the customers ideas, suggestion and needs. Customer involvement in innovation also results in value co-creation. Innovation itself is determined by different factors such as the needs of the customers, tastes, interaction with the users and the innovation produced by the users. Involving customers/users in the producers of innovation is very benefiting for any organization, because of the useful knowledge collected. The knowledge goes toward identification of users needs and desires which result in product improvement or development of innovative solutions. Nicolajsen and Scupola (2011) discuss the three different types of customer involvement which are consist of customers as a resource (1), customers as co-creators (2) and customers as users (3). It is argued that involving the user can have a positive influence in all the stages of new service development, even when the initial involvement was in idea generation and idea screening. Most firms involve users in strategic planning, personal experience and test marketing which have minimal impact on product and service development.

## 2.2 Value Creation

Zainuddin, Dent and Tam (2017) specify that value creation is a paradigm which involves different stakeholders involved in a consumption process, working together at various stages to create value. Value creation was initially conceptualized as a firm-oriented concept. The rise of service-dominant logic devised by Vargo & Lusch (2004), has driven the evolution of the concept towards consumer orientation and consumer dominance. Value creation seeks to explain the development

that leads to the creation and experience of user value. It is a concept of economic marketing because it is characterized as "an interactive relativistic preference experience" (ibid). Figueiredo and Scaraboto (2016) through the concept of collaborating consumer networks, set out to explore the substantial distribution and digital objects between the user connectivity in order to understand how value-creation is integrated and how outcome is shared between actors. The authors explain that the nature of development is in how the actors share network assessment that emerges over time, space and create different kinds of potential value. Likewise, Balka et al. (2014) indicate that advancement in digital communication and technology have resulted in emergence of communities across different industries and as a great source of innovation. These platforms of communities are often for users but could involve other parties (Baldwin and von Hippel, 2011). Moreover, in most cases the members possess valuable knowledge which can be used to develop or improve new designs independently by applying most suitable skills for development (ibid). Baldwin and von Hippel describe these communities as important and valuable resources for knowledge collection for all organizations (ibid). The communities remain outside the firm's boundaries, because the organization keeps hierarchical control over them. The firm integrates the inputs towards the process of innovation. It appears that integrating communities as sources of innovation can be complex. Therefore, organizations require explicit capabilities to recognize, access, and incorporate this knowledge and, at the same time, focus on value creation opportunities during the process.

Gupta *et al.* (2012) state that interaction is very important in exploring the users' knowledge, experience, beliefs, desires and needs in order to understand their priorities in life. By interacting with the users, they become evolved in the value-creation activities, continuously generating knowledge. Interaction occurs through a mutual learning process, with the users who provide inputs that are key to product and service development. Gupta *et al.* (2012) use the model presented below, to explain how value is created through company-customer interaction.

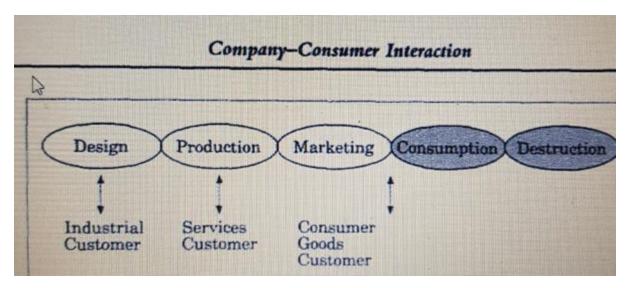


Figure 5. "Customer/consumer entry into the value-creating process in different markets. Figure inspired by Carlsson (1990) and Cummessom (1993).

Furthermore, in the service area of business-to-business, the main focus is on the interaction between producers and customers. However, in the process of value creation of customer goods, the users are usually involved from the early stages, all the way up to the market level (ibid). In that context, the value-creation process consists of all of the activities that start from product design to final development of the product (ibid). According to the researchers, traditionally involvement differed. Gupta *et al.* (2012) highlight that, for products, users become involved when goods are ready for purchase. However, in services the involvement occurs during the process of production, making the customer part of the production process. Likewise, in some markets where organizations have few users, the interaction may start at any stage as early as design or development of service. In the service markets, where processes are emerging all the time, it is difficult to specify to what extent or stage a user is part of design and production process. Firms should take a closer look at the process interaction to evaluate how to promote traditional users early. It is necessary to study the interaction from the other end of the process and learn how to promote corporate interaction in the traditional consumer domain of consumption and destruction (ibid).

Balka *et al.* (2014) give credit to open innovation by stating that an organization can benefit from it in different ways. Opportunities to build upon inputs that come from external actors are rising, and these can subsequently lead to value creation. Open innovation allows for short-term

involvement of external resources and ability to access unknown opportunities. Nonetheless, it can lead to important effective process in R&D. Likewise, in the market perceptive, it gives signs of activities of competitors and users due to its subjectivity to external networks. Organization can use some of these actors to their advantages. Especially, in open innovation systems, because online innovation communities are increasingly becoming a major focus of research (ibid). Echeverri & Skålén (2011) argue that the key to marketing research effort is to understand how value is created and differentiate the two main types of value formulation. First, the non-interactive value formation that dominates the value created by providers and consumed by users. This type of value can be conceptualized and exchanged. Second value is the value created through interactions which depends on co-creation when interaction takes place between the provider and the user.

# 2.3 SD-logic Co-creation and Co-destruction of value

According to Vargo and Lutch (2008), the term co-creation of value was invented by Vargo and Lusch (2004) who argued that firms form their value propositions and customers subjectively create value from these. Co-creation is a part of the service dominant logic (SD-Logic) which distinguishes between two types of resources - operand and operant (ibid).

The operand resources are tangible, i.e. they can be natural resources. The operant ones are non-tangible and can include concepts such as skills and knowledge. The authors explain that constant and dynamic exchange of operant resources that imply abilities, skills or specific human knowledge, that create opportunity to benefit the receiver (ibid). Likewise, Echeverri and Skålén (2011) argue that operant resources are key to competitive advantage and co-creation of value. They mention that SD-logic is a critique of the goods-dominant logic, which emphasizes operand resources as central to value creation, stating that such a view only focuses on co-creation of value (ibid). Arguably, firms and customers can also co-destruct value. Especially when a service does not live up to a customer's expectations and needs.

The experience or expectations of customers is always subjective. While there is no "one size that fits all", Vargo and Lusch stress that "a service centered view is inherently customer oriented and relational" (Vargo and Lusch 2008). Mills and Razmdoost (2016) discuss how Vargo and Lusch (2004) previously paid attention solely to the customer, but later developed a principle that

replaced the primary premises. They state that Vargo and Lusch (Vargo and Lusch, 2015, cited in: Echeverri & Skålén, 2011) extended the principle to be more inclusive; not only for firms and customers, but to include a wider "appreciation of "value-in-use" and "value-in-context" (ibid). There was also a shift of value from a B2C and B2B settings to the other of an actor-to-actor (A2A) that melted the focus on a single actor. This undoubtedly strengthens the principle that value creation occurs when networks and diverse actors interact by the means of communication systems; in this way resources and services are integrated with each other. Mills and Razmdoost (2016) also argue that Vargo and Lusch's (Vargo and Lusch, 2008, cited in: Mills and Razmdoost, 2016) conviction on value creation is that all actors co-create value. Meaning that co-production is not possible if the system is closed for interaction of the customers or to the provider. Co-creation only occurs when two or more actors affect each other or when the actors interact by means of a dialogical, continuous process (ibid).

It is important mention that sometimes a system chooses to be closed for the customer interaction during design production stage because of complexity, fear of loss of control or lack of user experience of actors involved. Value is not only co-created, but it can also be co-destructed as result of negative interactions between actors. For example, if a service provider's actions do not meet its customers' expectations, other users may not use the service as intended, resulting in failure. Value creation is not a given factor, but a correspondence that happens through negotiation, misinterpretation and system that require a process to solve value destruction (ibid).

Vargo and Lusch (2008) argue that emphasis on the customer as the co-creator of value and the network for value creation is more indirect and not obscure. Interaction opens the nature of exchange within a network. It usually emerges over time by trading skills indirectly for other skills in vertical market systems which can lead to bureaucratic hierarchical organizations. Value networks always open important nature of interaction during the process that can emerge unexpectedly (ibid). Firms continue to integrate and alter these micro-skills and competences that are not seen as important in the early stages but lead to complex services that are driven by market needs. Therefore, it is argued by most literature that interaction and networks are considered as vital, explicit and part of the nature of value creation in case of S-D logic (ibid).

# 2.4 Knowledge as part of value creation

Knowledge is a key resource and if well identified it creates economic value. Jeannerat and Kebir (2016) discuss how knowledge in its different forms, subjects and dynamics has been conventional from different literature. The authors state that, knowledge has been important for social innovation since the late 1990s (ibid). Arguably, knowledge in its traditional understanding was not considered as a factor of change. However, recently it has been recognized as a key and an important resource necessary for economic value creation. Jeannerat and Kebir (2016) continue to discuss the two different ways knowledge resources can be conceptualized. Firstly, knowledge is believed to be a given factor where it is inherent with prearranged results in production and market competition. Knowledge is also constructed, developed, maintained and valued within individual, relational and institutional settings, where it is entrancing and emerging over time and space. Secondly, knowledge is not a given economic resource, but it is embodied by other materials such as machines, books or technology that require human involvement and social relations and practices to create economic value (ibid). This kind of knowledge is shared and altered within social communities, where it adds to the structure of these communities, as well as their significance and identity. Jeanner at and Kebir (2016) argue that, knowledge develops and emerges actively, being reproduced and renewed over time. It is generated, expanded and mixed in a dialectical process of creation and destruction (ibid). Lastly, knowledge can only become an economic resource if it is exploited at the production level.

Olavarrieta and Friedmann (2008) state that the evolutionary approach to strategy for knowledge is more active in nature, where it is reflected in the firm learning, its findings, adaptation and strategic choices that are the major qualities in the firm and industrial evolution. Likewise, there are three main suggested backgrounds of a firm's long-term success:

- the firm's capability to generate innovation,
- having strong barriers for competition entering the market by imitation,
- possessing the capability to actively carry out innovation, to deter imitation.

Learning in an organization is the core cultural backbone of all market organization (Slater and Narver, 1995, cited in: Olavarrieta and Friedmann, 2008). Mentioning that, Market Organization (MO) reveals a culture and promotes organization learning behavior that can help develop and uphold profitable relationships with the users. Market-driven culture encourages value creation in information systems, by linking the resource-based approach to the market strategy. This often

gives The organization gets advantage of outside opportunities to create market-sense, user link and connecting the system opportunities capabilities. The acquired information, distribution, interpretation and storage construct advantageous relationships between the organization, market and the activities embodied in it (ibid).

# 2.5 Digitalization as a means of value creation

Camacho and Fritsch (2012) discuss and state that digital transformation is growing rapidly and is changing the ways of life. Traditionally digital transformation meant the use of computer and the Internet technology to improve efficiency and effectiveness of economics for value creation processes. However, in modern sense it is understood as the changes that come with new technology as a whole. Digitalization changes the arrangement, as well as operational and interactive processes of every organization. Likewise, digital transformation changes the system of wealth creation and it is, for certain, that it has an obvious, long-term revolutionary impact on economic systems, commercial actors as well as increasing impact on individuals and society. Camacho and Fritsch (2012) continue to discuss how digital transformation lowers the cost of interaction in information exchange and coordination for economic systems and market interactions. Digitalization potentially creates value through more exchanges. It also creates a fluid market that can encourage competition, due to easy access to information and more irregularity between economic actors. In the current environment, data is easily accessible everywhere on-thego which leads to massive data processing, storage, and recovery processes. The biggest challenge is to investigate and understand patterns in the enormous data volumes in order to act on a decision (ibid).

Zott and Amit (2017) argue that digitalization creates new technologies that promote product and service innovation. These technologies include faster personal computers, better smartphones and wearable gadgets technology. The technology is getting "smarter" in everything and rapidly growing on the global scale. Digitalization is changing lives in an extreme way. It does not only impact the product and service, but also organizational procedures and systems used to create more value. Given the fact that digitalization is growing rapidly, new ideas are inevitable. Business model innovation is used by a company to completely reshape its business structure.

Furthermore, digitalization is a vital choice of strategy for entrepreneurs and managers because it outlines how the company extracts the networks of other companies, institutions and customers in

that industry. In some cases, it connects back to previously unconnected or disconnected actors and links the current actors in new and different ways. Digitalization emerges and makes way to new digitally supported activities and can be crucial for fastening invigorating/enhancing a company's competitive advantage in the digital world. Besides, it plays a huge role in value creation for the stakeholders. In the technological era, competition is fierce, and companies are undertaking different complementary activities to reconfigure their customer value propositions, thus transforming their operations in order to increase greater customer interactions and collaborations (ibid).

According to Berman (2012) and Matt et al. (2015), companies focus on digital transformations to understand what customers value most and how transformation alterations to operating models can help them achieve competitive differentiation (Berman, 2012; Matt et al., 2015). Berman argues that transformation by using mobile connectivity and social media have resulted in an explosion of data with tremendous flows of information that have allowed companies to gain competitive advantage (ibid).

# 2.6 Identities of interviewees and co-production of information

In total, five semi-structured interviews were carried out to some key informants. Two of them were from top management of the organization in diabetes treatment - the chief head of studies and head doctor at Steno Diabetes centre and the Director, Global Patient Relations Corporate Affairs at Novo Nordisk A/S. The other three interviewees were patients. One of them was a key informant because he has been living with the disease for over 30 years and has been involved in clinical trials for the diabetes treatment. Each of the interviews was approximately 30 minutes long. They were undertaken with the purpose of gathering information and perceptions of how Novo Nordisk involve their users in R&D, as well as pick up unexpected opinions on the topic. Glover, (2018) argue that the semi-structured interview style is suitable because of the flexibility for researchers who are looking for data that can help interpret the context of research topic. Our goal in this thesis was to get enough data to conceptualized with our theories of the thesis in detail. Due to time constraints, the analysis of primary data collection is weak in interpretation. A set of multiple secondary data sources was used, making the thesis highly subjective. Only 2 interviews with professional informants and three interviews with patients' informants were

performed, and this is not sufficient to give a better interpretation and understanding of users' involvement in diabetes treatment.

From the interviews with the doctor and head of studies, we were able to establish that the patient is considered the main player in the treatment programme. Moreover, it is the patient who directs how he or she wants their treatment to be carried out, regardless of the brand of the medicine or its producer. The expert's role is to treat, help manage and give advice on available treatments in order to assist the patient in handling the disease.

The findings from the second interview with an employee from Novo Nordisk, indicated that the user involvement has been gradually improving with the help of The European Patients' Academy (EUPATI) and Disease Experience Expert Panels (DEEPs). It is, however, still in the early stages and the company continues to experience complexity. Therefore, the employee was not able to share sensitive information which would help to fully understand how the company involves the patient. That would have undoubtedly provided with better insight. Instead, the informant directed us to EUPATI to learn more on how Novo Nordisk is working with other partners on all categories of user involvement and value creation, as the system transforms to co-create value all actors involved. This helped us identify how the involvement is changing. Bak (2011) states that the reputation between data concepts and connection concepts is defined and explained by how important the users are involved.

# 3. Methodology

### 3.1 Introduction

After reviewing an extensive body of literature to identify the varying means by which businesses embrace new technology and strategize their production to give their target customers value for money and establish a satisfactory long-time relationship, this section will discuss the methods adopted to identify how Novo Nordisk's customer centric approach to business influence their innovation process. Drawing mainly on primary qualitative data, the section will justify the choice of methods and how the choices affect the analysis of the data and thereby influence its interpretation.

The discussions in this section begins with a detailed presentation of the philosophy of science we adopted for the thesis. The section is proceeded with the derived methodology found suitable for extraction of necessary data for the purpose of this thesis.

# 3.2 Research philosophy and paradigms

Bak (2011) highlights the importance of research paradigm as the world views or beliefs or the philosophical grounds that guide the researcher to conduct an effective research. Philosophies that have dominated the literature over time are 'positivism', 'realism' and 'interpretivism'. For this research paper we have chosen interpretivism as the guiding paradigm. Bak argues that the social world is more complex and thus, it cannot be generalized or theorized by natural and physical sciences (ibid). Comparing to hermeneutics, the world is seen as a social construct with subjective meaning and intentions, where it gives a natural way of collecting data with complex encounters such as time wastage unnecessary resource utilization during data analyzation and its interpretation. Choosing the right paradigms helps in the methodological technique chosen. Morgan (2014) argues that the literature treats paradigms as all-surrounding ways of experiencing and thinking of our world in relation to our beliefs on morals, values, and aesthetics.

Johnson & Gray (2010) argue that human and social science world is believed to be comprised of different and complex realities. It is agreed that human thoughts, experiences, feelings and emotions are subjective to them. Quantitative approaches suggest that, there are objective realities that impact the human world, which means that subjective and intersubjective reality are embraced in research studies as they reflect on their own views and understanding of the real-world phenomena (ibid). Saunders (2009) also claims that the business world is constantly changing and thus, it is complex and unique. Moreover, the business environment seen today may not be the same tomorrow.

The research following the interpretivist path is more subjective and is focused not only on the 'what' question, but also on the 'why', 'how' and 'what if's (ibid). In this thesis, innovation is part of company resources that continually develop or change due to technological development. While looking into the Novo Nordisk case of diabetes treatment (which cannot be generalized due to different kind of the disease type and treatment), we will discuss different aspects of user involvement, insulin and tablets, knowledge sharing, digitalization, and value creation. Thus, the questions like 'what', 'why', 'how' and 'what if' will always be our primary focus throughout the

analysis and interpretation of the data. Furthermore, the existence of multiple realities has been taken into consideration and full understanding of the topic has been acquired. Over and above, the complexity of the subject has been captured. Hence, the use of interpretivism paradigm in this research paper is suitable to answer these questions.

Kushniruk and Patel (2006) state that qualitative methods are useful in deciding how and why specific outcomes occur. The qualitative ones have assisted our research in trying to understand and building a theory on how a medical information system affects the organization and its actors. Besides, in our case, they have provided with insight into why diabetes treatment is always changing and how it is developing. Lastly, qualitative methods are applicable testing our theory of user involvement.

## 3.3 Role of the researchers

Gringeri, Barusch and Cambron (2013) state that where interpretivist reasoning is applied, researchers should reflect on their own worldviews since this can affect the study. In qualitative research, the researcher can never be objective. Thus, self-reflecting is a part of this research design. Qualitative researchers often describe the ambiguities and complexities of extracting meanings from ambiguous and perplexing data (ibid). The authors also argue that, when interpretation is at the core of research, it is significant to admit that the role of researchers' "values, histories and interests" in the production of data can affect the results (ibid). This is due to the fact that data collected during the research process may be interpreted in various ways by different researchers. In this paper, we have used a large number of articles that were peer-reviewed to cross-check the available information on Novo Nordisk patient involvement in diabetes treatment development. Then, we tried to reflect on their understandings of the situation which has inevitably impacted the study. We have done to the best of our ability to reflect on our own worldviews during the research, to make it as objective as possible.

We have done this by first asking ourselves "What do I know through my engagement with the world? How do I account for myself (history, social positions)", to help the researchers reflect on why the phenomenon is important to study and examine the ways the study might proceed (ibid).

## 3.4 Methods

With interpretivism forming the epistemological framework of this study, the exploration of how businesses involve their customers in their innovation process will be studied in the context of Novo Nordisk and its customers. Reflecting on similar explorative studies conducted in the field of user involvement, interviewing has proven to be the ideal method to solicit information from both the decision-makers at Novo Nordisk and its customers. Although methods such as questionnaires and focus groups could have been adopted for this study, the choice to use qualitative interview was informed by our quest to acquire detailed information from respondents. As observed, semi-structured qualitative interviews present us with the opportunity to gain clarifications to answers through follow up questions.

## 3.4.1 How the qualitative interviews were conducted

Bearing in mind that the manner and environment in which interviews are conducted affect their outcome, we employed precautionary measures to provide the best possible conditions for each of the interviews to prevent possible alterations. This section discusses steps we adopted before, during and after the interviews. In the process of planning, conducting, and analyzing the interviews a few measures were considered. These are described in the subsequent.

# 3.4.2 Choosing appropriate participants for the research

The intention for the study determined who was interviewed for the study. Therefore, for this research purposeful sampling was used. Potential participants were chosen to represent the population to be studied with the aim of reaching out to a reasonable cross-section of people who work at Novo Nordisk. Connecting with the participants early through the phone, e-mail or in person, helped identify beforehand, if they were willing to participate and were available for the interview.

# 3.4.3 Preparing a research protocol

The purpose and steps to be followed during the study is the research protocol. Preparing the research protocol before the study aided us in thinking critically throughout the study. It helped devise proper interview questions, as well as anticipate the possible follow up ones. It provided

information about the nature of the primary and secondary research questions and explanations that enabled interviewees to elaborate on their answers. An appreciation message to the participants was included.

## 3.4.4 Devising useful interview questions intended to capture the data required

Writing appropriate interview questions was essential. The questions were to be conversational in tone; short and clear. Technical language and jargon were avoided.

The three types of interview questions used to obtain information included:

- main interview questions,
- planned follow-up questions or probes,
- spontaneous follow-up questions.

A useful final question that was also essential was 'is there anything else you would like me to know?'' In some instances, this sort of a question was actually the starting point of the real interview as the answers to it proved to be very revealing.

We believe it is also worthy to note that an interview guide was sent to the participants days before the actual interview took place. This gave participants good time to prepare and reflect on their answers.

# 3.4.5 Creation and exhibition of affinity with the participants and attentive listening

Writing good research questions is important however, being a good listener is a vital skill as well. Close attention was paid during the interviews.

Additionally, ethical issues associated with the conduction of interview, including privacy and consent, timing of the interview, the preamble and managing the interview were key steps considered.

#### 3.4.6 Available methods and alternatives

There are three major qualitative research methods:

Participant observation - involves participating and observing places, practices and people.
It is ideal for collecting data on naturally occurring behaviors in their usual contexts.

- 2) Focus groups effective in eliciting data on the cultural norms of a group and in generating broad overviews of issues of concern to the cultural groups or subgroups represented.
- 3) Expert interviews optimal for collecting data on individuals' personal histories, perspectives, and experiences, particularly when sensitive topics are being explored ("Qualitative Research Methods: A Data Collector's Field Book," n.d.).

## 3.5 Justification of method

For this research work, expert interviews and participant interviews were used for data collection, since the study required complex questioning and considerable probing.

Expert interviews explore a person's specific knowledge and experiences, which result from their actions, responsibilities, and obligations connected to their functional status within an organization/institution. This method was employed as one of the data collection methods for this research work because it is the cornerstone of present-day health care research and can be utilized by both experienced and new researchers to accumulate data for research.

In health care, interviews can be used to obtain information about people's experiences of their illness, and of the services they receive or to look at health care practitioners' needs and attitudes to their work which can lead to improvements in patient care and direct clinical practice (Littig, 2013). It is an ideal way to find information required to solve research problems in the area of humanities. The purpose of expert interviews is "to obtain additional unknown or reliable information, authoritative opinions serious and professional assessments of the research topic" (Libakova & Sertakova, 2015). Questions in this type of interviews are open in nature which allows the experts to express their point of you on the issue under study (ibid). Due to the fact that respondents are highly qualified in regards to questions asked, the need to do perform additional screening is eliminated (ibid).

# 3.6 Sample size

There was the need to gather in-depth information on how the management at Novo Nordisk employ user involvement. This required us to conduct expert interviews with carefully selected management staff of the company who are part of the decision-making body. Charline Coquerel, who is the Director for Global Patience Relations of Novo Nordisk was selected for the interview.

Also, in order to get a holistic understanding of how Novo Nordisk is guided by user involvement, it was necessary to include their customers who are patients. In this regard, we selected diabetes patients who, due to the chronic disease, knew and had information about Novo Nordisk diabetes products. Due to the confidentiality agreement made between the patients and us, their identities remain anonymous throughout the entire analysis.

In addition to the customers, Dr. Ulla Bjerre-Christensen, who is the Head of Education Department at Steno Diabetes Centre Copenhagen (SDCC) was also selected to provide her expert opinion on how the diabetes product are selected for customers. Her comprehensive knowledge provided us with insights on how customers' preference of products informs the innovation process of Novo Nordisk.

In all, we settled five participants as our experts for this study. Taking into consideration the busy nature of the experts' work who had been selected for this study, we conducted four face-to-face interviews whereas the last one was done via telephone.

Before the interview, we chose a setting with least distraction. Although the experts had prior knowledge of what the interview was going to be about, we reiterated the purpose to refresh their memories. That was done to ensure that we receive the data necessary for this study.

We informed the participants about terms of confidentiality and the format and the duration of the interview. To establish a rapport and gain the trust of the participant, our contact information was provided to the participants. Following that, we gave the interviewees an opportunity to clarify any doubts they had about the interview. The interviews were properly recorded with additional notes made.

# 3.7 Semi-structured interview approach

During each interview, we, as the interviewers, ensured that respondents remained involved in the interview. We asked about facts before discussing controversial matters. Moreover, fact-based questions were interspersed throughout the interview. Besides that, we posed questions about the past, present and future experience with Novo Nordisk.

The major part of the interview was allowing the interviewees to provide us with any information they intended to add. Besides, the participants were able to give their impressions of the interview which was very informative.

Occasionally we checked the tape recorder to assure that it was working properly. To enable the respondent to think through the question and provide specific answers, we asked one question at a time. Any observations made during the interview were also documented. We took notes to highlight major themes in the interviews with each respondent. Following the interviews, we compiled the notes for content analysis. Transcription reports were assembled into one report for each participant to generate the most accurate representation of their comments.

Drawing from the philosophy of science, the study employs deductive reasoning in the interpretation of data. Content analysis was conducted for each interview.

# 4. Analysis

## 4.1 Introduction

User-Driven Innovation is the central focus of many organizations, including Novo Nordisk. As shown in the literature review, modern market innovation is the driving force for companies' achievements and competitiveness. Therefore, organizations are looking for ways to boost efficiency and value creation for their users. Rocheska et al. (2014) argue that the interactive nature of innovation and preoccupation of outside knowledge is rapidly growing, and it is important for organization to improve its innovation performance. Most organizations are searching for different approaches to innovation in their Research and Development (R&D) departments. Such as utilizing the potential of other resources to improve innovation. To do this, most companies are using various external actors to generate better solutions for innovation and keep up with competition.

Rocheska et al. (2014) argue that users' role does not end with organization's innovation design that match the user's idea proposals and requirements. As a matter of fact, they are part of the continuity of the organization. Organization innovation occurs when the user involvement is collaborated, and value is created. Likewise, organization's innovation process is decided by perceived needs, tastes and requirements of users that emerge, to a achieve better innovative solutions. Moreover, user involvement helps building a strong interaction with the users to value co-create and share knowledge.

In the following sections, we present main themes that emerged from our theoretical data collection and interviews. These comprise of: User Involvement, Value creation using Co-creation and Co-destruction, Digitalization and Knowledge-sharing as concepts of value creation.

### 4.2 User Involvement

We will focus our analysis on patients who are diabetic and their user involvement in the healthcare and social care education at Novo Nordisk (NN).

Our research has concentrated on direct user involvement in diabetes care. Particularly, on User-Driven Innovation in insulin treatments, that began 85 years ago.

We started by investigating the role of the user in development of insulin treatments. However, soon we discovered that diabetes is more than just insulin. Therefore, our aim is to explore how patients are involved in healthcare and pharmaceuticals, to bring positive change in diabetes treatment in general. In order to understand it better, we performed context search of literature on User-Driven Innovation (UDI) in general. It became apparent, that the theme of user involvement was used more. Informants indicated that patients were involved multiple levels of innovation with the help of EUPATI.

Warner et al. (2018) define 'a patient' in different terms. To understand the potential roles of patients used by EUPATI, they state that a patient can be an individual with personal experience of living with a disease who may not have technical knowledge in R&D but have a role that contributes to their subjective and treatment of the disease through experience (ibid).

During our interview with a patient (Appendix 3 (P)) we learnt that P has had the disease for 30 years and was among the first patients to try the first insulin treatment. The informant had more experience of the disease and was aware of what treatments were available for him. Throughout the years, he has changed the insulin type to meet his needs. As P stated,

"Right now, I take NoVo-rapid insulin and before that I took Lantus insulin, it is not Novo's product, different kinds of insulin through the 30 years. But now I take one, because I have pump now and I only use one kind of insulin because it is easy for me". (Appendix 3)

The other type of patients are 'carers'. These are individuals who support patients - such as family members or paid helpers. Besides, there are 'patients advocates' who support the larger population

of patients living with the specific disease and may work alone or be linked to an organization. The patient informant indicated that he was not in a club or an association. However, he has registered with diabetes.dk, where he receives information about the disease through a monthly subscription. The online platform helps him learn more about the news on diabetes disease, suitable diets and allows P to interact with other patients.

Patients can also be Patients' Organization Representatives or Patients experts. The later, include persons or doctors who help the patients manage the disease due to their expertise in a specific disease. They possess technical knowledge in R&D and regulation in that disease acquired through training (Warner et al., 2018).

Our informant (U) stated how her job as a doctor was to inform the patient about available treatments and to instruct the patient on how to properly manage the disease.

"We educate patients about their disease and tell them about types of treatment available without saying the specific company is for example Novo Nordisk product. From my perspective, to the patient it is unnecessary information because if it is a Lilly, Novo or saniona insulin it does not matter" (Appendix 1).

Sometimes there are reservations to involve individuals or patients due to confidentiality of the disease and therefore having a managed platform that practices discretion definitely encourages patients involvement. EUPATI manages the interactions of patients where it has different ways to initiate activities that suit individual patients (ibid).

In this thesis we talk about the individual in terms of patient's involvement and how their inputs have affected the industry. Rhodes (2012) stresses that user involvement in healthcare and social care education is rapidly growing. This is due to the user-focused approach in their care, which is pushing for more action from the health actors in their own agendas. There is a need to give the patients and public more information, choices and work with them to deliver a high-quality care for the patients. During our interview it was established that

"(...) most of pharmaceutical companies try to work with patients panels to discuss with them and using them as a sounding board specially related to the devices and to the timing" (Appendix 1).

As a matter of fact, European Patients' Forum (EPF) was started in 2003 by 13 patients (Endev, 2013). According Endev, patient empowerment is one of the major areas of focus in healthcare and patients are seen as more than just their health condition (ibid). They have needs, expertise, values and rights just like other people without the disease. Patient empowerment is all about developing an environment that is patient-driven care where patients not only receive their care but where they ought to be considered as the most important member of their care team. The EPF focuses on health literacy & information, professional training & skills, self-management support, patient-driven technology solutions, patient involvement in patient safety, patient-centeredness in healthcare, patient involvement across the R&D lifecycle, and patient involvement in health policy (ibid). During the interview, our expert informant mentioned how the patients are the center and the driver of their care. The only thing on their minds is to get better and it does not matter what kind of brand the medicine is. The informant stated that

"what would be their biggest help for them [patients] and if you ask the patient with the chronic disease most of them will say it is for disease to disappear, so if you can give me either a tablet or insulin anything that will make my daily remembrance about my disease to disappear that would be the best for me" (Appendix 1).

Parsons et al. (2016) discuss how patients are more aware of their health and increasingly get involved in managing it by searching for health information in different platforms to be more knowledgeable about their health it. Patients no longer rely on the healthcare professionals for information about the disease. The developments have arguably changed the expectations of both the patients and health professionals on health management.

According to our informant from Novo Nordisk

"Novo Nordisk believes that to access healthcare is a basic human right and it should be of high quality" (Appendix 2).

Endev (2013) argues that it is crucial and the priority for patients to have a longstanding access to a reasonable high-quality, patient-centered healthcare. An organization should strive to remove inequalities and barriers that hinder good healthcare by involving the patients in the process in to understand the patients' needs and expectations better.

Novo Nordisk, like many other pharmaceuticals' firms, is working towards developing medications that are patient-centered. As Parsons et al. (2016) suggest, in recent years, pharmaceutical industry has been focusing on having medical Research and Development (R&D) that is more patient-centered.

In their research, the authors discovered that this could be influenced by the changing nature of patients' needs and expectation as well as looking for ways for sustainability of medicines (R&D) in the industry (ibid). The research revealed that 73% of employees in the industry believe that there is a need to change pharmaceutical relations and interactions with patients. At the same time, 85% believed that improving the patient-centers of medical R&D was the key for its sustainability (ibid).

As the market trends change, patients are more aware of their needs and in order to keep up with competition, Novo Nordisk are still learning how to involve the patients' inputs into the industry. Warner et al. (2018) describe that patients are more willing to be part of medicines development and they wish to be involved across all levels and functions of medicines R&D lifecycle from preapproval to post marketing activities of the pharmaceutical industry. Likewise, the authors argue that patient involvement ought to have clear rules, decisive procedures for it to achieve an effective (R&D) and a successful working system involving patients. These guidelines will erase potential conflict of interaction between patients and firms collaboration within the industry (ibid).

Novo Nordisk work with EUPATI to involve patients in all the processes discussed below.

## 4.3 Patient Involvement

Parsons *et al.* (2016) explain that historically, pharmaceutical companies primarily acted as financial sponsors for patient organizations, with little patients' involvement in the activities they were sponsoring. However, in recent years joint developments in cooperation trends for the pharmaceutical industry and other key stakeholders in medicines R&D and interaction of the medicines environment R&D are rapidly growing with more patients interested in involvement. This means that the pharmaceutical industry can no longer act solely as sponsors for patient associations. This arguably allows the patients to have access to knowledge and learn from the process of interaction, as they share common experiences. During our interview with one of the patients, he noted the he changed his insulin pump after seeing young people using it, when initially

he had thought it was only for young people. He made an inquiry from to the doctor who informed him that the treatment was for all ages (Appendix 3).

Warner *et al.* (2018) state that platforms like EUPATI are created to encourage patient involvement making it more patient-centred. They help identify new areas of research that promotes innovations ideas, to give a new understanding of how to solve problems and improve adequacy of new medicines to patients. EUPATI works with all age groups across conditions and these are referred to "patients" without focusing on disease-specific issues or therapies. The focus is, therefore, on the process of medicine development in general. Suggestions on particular information, age-specific or specific medicine interventions are outside the capabilities of EUPATI and are the responsibilities of the health professionals as well as patient organizations (ibid). Novo Nordisk is a partner of EUPATI that helps pharmaceutical industry to collaborate with user inputs for (R&D). Our informant from Novo Nordisk stated that

"EUPATI, so it is European public private initiative, Novo Nordisk is part of consortium of study plus partners and EUPATI for the past ten years also they have been very much focused on insuring that patients are involved in the development of new medication not only diabetes but medication in general and of course when you work with pharma, academic or regulators, it is a very complex system with a lot of rules and regulations, so EUPATI mission was primary to draw the lines of what kind of training and profile patients' needs to be free equipped to have a constructive dialogues with pharmaceutical industry, academics or whoever they needs to be engage with" (Appendix 2).

Novo Nordisk follow EUPATI's 4 guidelines on how to involve the user. The informant noted that EUPATI builds different profiles of patients on what and how pharmaceutical industry can involve them. Using these files and recommendations, Novo Nordisk as a contributor to EUPATI, benefits from EUPATI.

"So from our work with EUPATI we started to create our own network of patients that we call DEEP (Disease Experience Expert Panel) and also as the suggestion of the EUPATI we have developed kind of theory of the patient because patients comes with different kinds of expertise and experience with their own disease" (Appendix 2).

Likewise Haerry *et al.* (2018) state that, EUPATI has developed guidelines for all stakeholders who aspire to interact with patients on their medicines (R&D). Certain users may not be part of these guidelines due to some specific circumstances, national legislation or the exclusive needs of the type of interaction.

However, the guidelines should be adaptable, and each individual has obligations to use their best professional judgement while getting involved. The guidelines are disclosed in 4 separate documents, informing how to involve the patient. These guidelines outline areas as well as present opportunities for patient involvement. Besides, these are continuously reviewed and updated to reflect on new developments. The 4 guidelines are presented in the following sections.

## 4.3.1 Pharmaceutical industry-led medicines R&D

#### Patient involvement in medicines R&D Information to Protocol trial participants Trial Synopsis Setting steering new safety information Data & Safety Research committee Monitoring High expertise in Priorities protocol follow up Regulatory Protocol improving access Committee Affairs Design Investigators - benefit/risk Meeting scenning drop-out issues EPAR summaries match benefit/risk balance amendments · trial design unmet needs lay summary of in-/exclusion criteria remide. with research diagnosis procedures package teaflets updated safety challenges quality of life and pat opportunities can trigger amer patient-relevant reported outcomes eckded value ethical inner mobility issues/logistics Dissemination. Research Design Research Conduct Research Communication. and Planning and Operations **Priorities** Post-approval # - contribution to publications dissemination of research results to Medium expertise in disease area required visual design summary of interim. # results language Post-study dissemination in patient communication bravel exp Ethical support for Study Patient # family members. Review assessment of value Information reporting # - patient-relevant Fundraising patient priorities for research visual design Practical Health Considerations # - language Technology Informed Assessment

Figure 6. Pharmaceutical industry-led medicines R&D Warner et al. (2018)

Consent

Warner *et al.* (2018) give suggestion of values to be adopted while engaging patients in the industry-led medicines R&D. The suggested values are applied to all levels and these are:

- Relevance The patients are knowledgeable, experienced; they match unique requirements that can contribute to the industry-led R&D.
- Fairness The patients should have similar rights to other actors and have admission to knowledge and experience. That is done to empower them through effective involvement. Patients are capable of adding value to R&D processes.
- Equity For patients to be involved in medicines R&D and achieve equity, they must understand the different needs of patients with different health issues and be able to balance them alongside the requirements of industry.
- Capacity building The processes of involving patients brings awareness of existing barriers to patient-involvement in medicines R&D and develops ability for collaboration of patients and research organizations.

Arguably, there is a need and greater advantage of patient involvement in medicines R&D in the industry. There is an increasingly action call for pharmaceutical enterprises to partner with patients in the development and lifecycle of medicines (ibid). Rhodes (2012) adds that patients' involvement is set to increase areas of healthcare education and public engagement. Furthermore, patient involvement in the industry can only work if it is founded on authenticity and trust between the parties involved and have friendly requirements that are comfortable with established patterns of engagement for all parties (ibid).

#### 4.4.2 Ethics committees

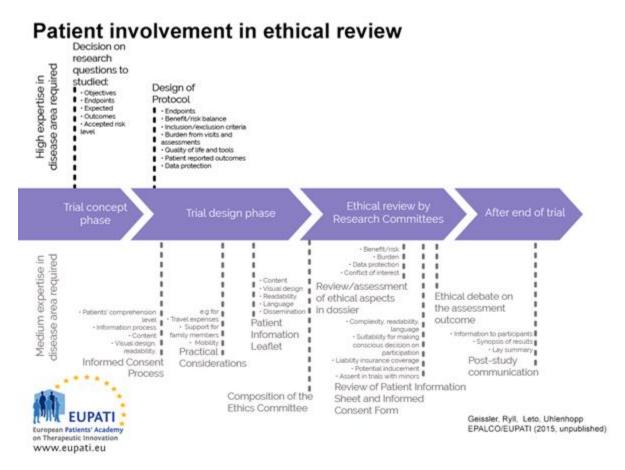


Figure 7. Patient involvement in ethical review of clinical trials, Klingmann et al. (2018)

Klingmann *et al.* (2018) argue that in order to have a good clinical trial design, a sound collaboration of ethics and science should be present. The decisions regarding the design should incorporate all trials, even if it is for new medicines that are to be compared to other medicines, or a dummy. The design should have clear guidelines for the participants to be selected and clearly set what kind of tests and assessments are to be done and how often. Any potential risks or harmful side effects should be made aware to the participants. Arguably, the authors state that the risks and side effects should balance against the potential benefits for the patients involved and to be worthwhile. Additionally, confidentiality and privacy of patients information is vital. It should be the doctors' priority to protect it, and they should do their best to inform the willing patients what to expect in terms of risk and benefits before they can decide to be part of the clinical trial (ibid).

Our informant from the diabetes centre described how pharmaceutical companies approach trial awareness:

"One thing is for trail to be sufficient and other thing is I have privacy with the patient if Novo Nordisk want to find out about their specific products they will normally do surveys, they could also some in doctors ask on all over whole term, what are your patients with AVNC, but it is not a routine for us to call the producing company, you need to do this. I could call them and say you need to do better" (Appendix 1)

Patients' benefits from the involvement can include:

- first to access new medicine in the market,
- better diagnostics,
- supervision that comes with the new development of treatments over the patients with similar diseases at a zero cost.

Moreover, currently the decision to involve patients is not always standardized and neither are the clinical trials in many organizations. They are subject to a strict framework with legal regulations because the trails need approval from competent authorities. This can take time and is sometimes complex (ibid).

Nicolajsen and Scupola (2011) argue that, although customer involvement in the development has the potential to lower hesitation to develop products, it requires active dialogue between both participants. They quote Lundkvist and Yakhlef (2004) who argue, that overall there is a need for a shared language and a shared approach for service providers and users to make collaboration between them possible. It should be set on ground of mutual understanding that there exist benefits for both parties involved. Most of the time, these procedures of collaboration are rarely clearly specified beforehand. Arguably, it is of substantial importance for social contracts to be formed as informal agreements that are based on trust between the actors mutual trust. These will result in long-term relationships with customers when involving them in the decision- making process.

Our informant from the diabetes centre (U) informed us how they raise awareness of trial opportunities. They ensure all patients are informed and based on the information they can decide if they want to be part of the trial. U stated that:

"Yes, we will say that we have this trail going on and you would need to fill certain criteria to go into that trail. But if you are interested you will go and have a talk with the trail manager and then that will be a separate thing to do" (Appendix 1).

#### 4.5.3 Regulatory authorities

#### Documents for the Public Package Leaflets Safety **EPAR** summaries Communications Package **Public Summaries** Risk Management of Opinion Plan summaries Post-Regulatory Procedure Pre-submission Evaluation Authorisation Marketing Orphan Designation Paediatric Scientific Post-Marketing Investigation Authorisation Application Plan Evaluation dmission: Committees and Working Parties CHMP CHMF CHMP COMP **PDCO** CAT SAWP PRAC PRAC CAT SAG SAG CAT = Committee for Advanced Therapies PDCO = Paediatric Committee CHMP = Committee for Human Medicinal Products PRAC = Pharmacovigilance and Patient Input EUPATI COMP = Committee for Orphan Medicinal Products Risk Assessment Committee

SAG = Scientific Advisory Group

SAWP = Scientific Advice Working Party

Outgoing Document

#### Patient Involvement at the EMA

Figure 8. Regulatory authorities Parsons et al., (2016)

EMA = European Medicines Agency

EPAR = European Public Assessment Reports

ropean Patients' Academy

on Therapeutic Innovation www.eupati.eu

European Medicines Agency (EMA) declares that Novo Nordisk follows the EMA guidelines to engage interactions between patients and medicines regulatory authorities related to medicines for human use. Parsons *et al.*, (2016) examine how the EMA has been interacting with its stakeholders since it was created in 1995. It is apparent that this "relationship" has evolved over time. Moreover, depending on which stakeholder is involved and the type of activity that is taking place, this interaction differs widely in groups (ibid). The group members include management board of EMA, scientific committees and patients/consumers. The agency's main goal is to successfully achieve the necessary and better collaboration between the regulatory authorities, national ministries of health, and other relevant stakeholders. It attempts this through active participation

and good interaction with patients, healthcare professionals and their representative organizations. The aim is to support the regulator in accessing real-life experiences and testimonies of diseases and gain prevailing information on medicine use to for better management of the diseases.

Sagsveen *et al.* (2018) affirm that to encourage good patient's health and guarantee high-quality services, involvement of users is important in modern healthcare. Practicing user involvement unquestionably brings potential benefits to patients and the industries. Example of such benefits include encouraging health behavior changes, empowering patients to take more responsibility of their own health, as well as patient satisfaction of treatment (ibid). Good policy initiatives and regulations will encourage active participation from patients and assist them in making decisions. Patients will be given freedom of expression, while simultaneously healthcare professionals will feel encouraged to deliver a service that promotes user involvement, both on an individual and system level.

As our informant from Novo Nordisk asserts that,

"We are really approaching this with pragmatic ways and really following I mean EUPATI is bigger work from many different stakeholders with different experience, with different project and views on that so, in state of else we advancing what we think is good, we have get on the knowledge of all these expertise, so we just took that framework as ok higher expertise most likely people involving patient expertise organization, people who are the blog and interact with many patients, so they just not carry their own expertise but they can also say ok if we are to discuss I don't know, how the people understand type to diabetes, how we can explain type to diabetes and progression of the disease differently, we would prefer to have a dialog with patients experts in a patients organization or blogger, because they can interact with many other patients so, they have a bigger overview of how people understand that" (Appendix 2).

Haerry *et al.* (2018) note that for promotion of transparency in patient involvement, agencies and patient organisations should plan to openly reveal their intended collaborative activities on annual basis. Concurrently, patient organisations must be committed to active interactions and ought to participate in "regulatory authorities" activities" (ibid).

## 4.5.4 Health technology assessment (HTA)

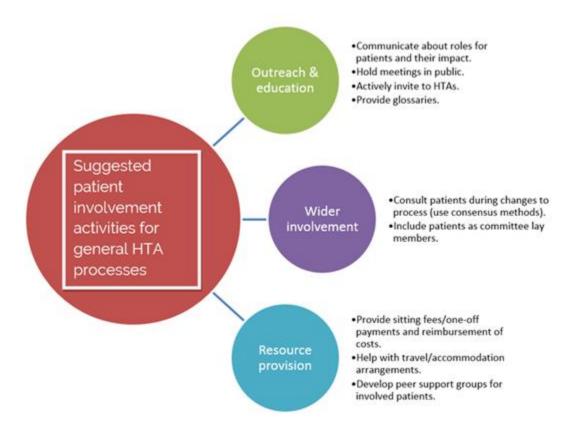


Figure 9. Health technology assessment Hunter et al. (2018)

Hunter *et al.* (2018) mention that, the main obligation of Health Technology Assessment (HTA) is to inform parties involved about decision made by healthcare policy makers. This is a well organised process of information-sharing that makes available data concerning healthcare technologies (medicines or medical devices). It also provides with reviews of both clinical effectiveness and cost effectiveness that needs to be shared by stakeholders. Moreover, HTA discloses information on social and ethical influence on healthcare system and lives of patients. The HTA process shares information even if the specific health technology will not be developed or used. In case it will be used, information on how to use it and what kind of patients are most liable to benefit from the medicine, will be provided.

The information assessments differ. However, they mostly cover the benefits and the risks of the medicine in question.

HTA assesses international evidence. These assessments can be applied to local health care structures, to understand more how new medicine can add value to health care system. Arguably, the medicine industry can no longer deny the importance of patient involvement in HTA. The decisions of HTA affect patients because they are important stakeholders. They have democratic right to be involved in the decisions that affects their daily lives. Therefore, HTA act as the mediator between scientific evidence and decision-making in medicine. Likewise, it is evident that patients provide information and insight they gather from different platforms that can impacts the medicine treatments development (ibid).

Using the above guidelines informant C from NN noted that, NN has developed and work with 4 theories.

"(...) so we have four theories, starting from an easy one, that is to work with our own colleagues at Novo Nordisk who are living with diabetes type one and type two or obesity or other chronic disease conditions we engage some of our colleagues on some project, we also have level three, we call them 1,2,3,4, where 4 is our colleagues, level three are our patients some time we just need to have normal person I would say living their life with this specific disease just to discuss primary materials. Level two other hide-outs and level one are all the patients who are actively engaged in the patient organization-led where there have a role as a patient expert and patient advocate so they are both in capacity to draw a bigger picture of what are the end needs for these disease which is important to understand the narrative of the need whether is from one person or the narrative of the community the advocate for involvement of medicine R&D" (Appendix 2).

However, *C* noted that the process is still in development, and the company continues to experience some complexity. It is still a learning process for all actors involved.

Geissler *et al.* (2017) point out the importance of acknowledging that not all opportunities for patient involvement have positive impact. There are some risks involved with tasks such as selecting patients, reviewing patient material and information disclosed in consent forms. On the other hand, there are some valuable aspects of Patient Involvement in medicine R&D that are more strategic for long-term impacts. They are, however, complex to implement. Research procedures

may need a culture change within academia and pharmaceuticals that will provide the opportunity of new benefits to emerge, leading to intervention.

## 4.6 Value creation

#### Value to patients and professionals including carers

Involving end-users has become the central part of strategy in public and private organizations with the aim to generate better user-driven innovative solutions to real-world problems (Martinez, Berkås and Fensli, 2016). In other words, to better understand the user's existing and future needs, end-users themselves must be involved. Traditionally, patients' needs and wants in relation to development of new products, were rarely researched (McNichol, 2013). It is no longer the case in modern medicine development.

The principle of the user-led method is to understand that the experience of patients living with certain conditions and carers bring diverse insights. It is equally as important as expertise of healthcare professionals. Patient involvement brings the experience to reality. Professionals are encouraged to make the best decisions on how innovations in medicine can benefit patients in managing their everyday struggles, remain independent, and get better quality of life. When patients are involved in innovation process a fortified perspective emerges. It creates an opportunity for healthcare organizations to design clear-cut medical tests and interventions, targeting improvements to patients' needs and wants.

Patients are the experts in living with chronic health conditions (McNichol, 2013). They are aware of it every single day and therefore they ought to know more on how to manage the physical, psychological, and social impacts that come with the disease(ibid). Without a doubt, their experience might differ from one individual to another. But all the same, they have a common, shared experience of living with a chronic illness.

During our interview, one of the patients emphasized how difficult living with chronic disease actually is. One has to find an easier and better way to manage the disease. As *P* explained:

P: "Is it convenience to manage it with the pump, is it easy for you to use that pump? No, it is not easy, it is not easy to get sick all the time, but you get used to it, yeah I think for me it is easy now, but people see what I do, they say oh wow...it is a lot you have to deal with" (Appendix 3)

Involving patients in R&D strengthens patients' ownership of the disease and willingness to be part of a changing process of their lifestyle (Sagsveen, Rise, *et al.*, 2018). The involvement of patients promotes the responsibility to plan their own goals of their everyday life. Furthermore, the involvement commits the patients to follow up the process of their health routine, benefiting professionals with easy management of the patient's' illness. Patients acknowledge their responsibility to do what is necessary to meet the goals and manage the disease (ibid). Reportedly, patients argued that they know themselves and the challenges that come with the disease best, and they experience negative consequences if someone else decides what their needs and wants should be (ibid).

Our informant U, as a healthcare professional, confirmed the aforementioned, believing that the patient is indeed the expert of their disease. Therefore, experiences of the patient are discussed and together with the healthcare professional, they find a solution.

When asked about the challenges of dealing with information shared by patients, U stated that

"To answer the question of challenges is way too broad because challenges depends totally specific. It might be psychological challenges, it might be physical challenges, it might just be challenges with the way the patient takes medication or the way medication works for the patients. So, whatever kind of challenge that he or she experiences, I would ask them when they come to the consultation, is there anything specific you want to talk about sometimes, they say no and other times they say yes I have this and this, my glucose goes high or low and we would look to that challenges that what can we do to solve it collectively" (Appendix 1).

Endev (2013) reported that involving patients in R&D, leads to patient empowerment with indepth information on their health concerns, experience of professional training and skills. Patients

also learn more on self-management support during the process which adds value to how to cope with chronic disease. Patient empowerment is brought into action through meaningful and systematic structures which absorb the inputs for healthcare improvement. Patients are important partners for quality, effective and competence improvement and must be recognized by organization.

#### Value to Novo Nordisk

Novo Nordisk involve patients who live with chronic diseases in its R&D to understand their experiences of the disease and challenges in their daily live in relation to the specific illness (novonordisk.com, 2019). R&D department enriched with patients' insights is capable of introducing innovation to provide better treatment, support the patients and improve their quality life.

Innovations in service delivery can lead to product innovation and vice versa. Martinez, Berkås and Fensli (2016) argue that business collaborations within the healthcare sector are not new and have existed for over 20 years, though in different ways. Commercial models play a key role in marketing and distributing of medicines where public healthcare initiatives and more research on effects of drugs is emerging (ibid). Pharmaceutical industry can indeed benefit from involving patients in innovation. The industry shall recognize a new market opportunity where there is a need and demand for new or refined products. Consequently, an enterprise may become a market leader or maintain competitive advantage with the new and better product.

Most innovations that involve patients from the first stage of development, have a high chance of success. That is due to the process taking into consideration the inputs and needs of patients. Moreover, it is possible to adjust at every stage of the involvement process, which ensures a more feasible chance of success and meeting the needs of patients (ibid).

Novo Nordisk (NN) continues to improve the treatment of diabetes, maintaining its leading position on the global market (Novo Nordisk, 2011). It takes pride in being the world's leader in diabetes treatment. Besides, since 1996, its business and management strategy has continued to be widely reorganized (ibid). This is to adapt the activities that add value to NN and focus on

resources that create value which lie within its R&D. This practice has resulted in increasing turnover and market share of NN over the years.

In 2018, NN stated that it had plans to restructure and reorganize R&D to accelerate the diversification and expansion of its pipeline (novonordisk.com, 2018). Moreover, the company intends to increase investment in transformational biological and technological innovation (ibid). As a result, the total number of workforces was expected to be reduced by approximately 1,300 before the end of year. Following these plans, NN's financial report for 2019 indicates increases in sales brought by the launch of new products in 79 countries and states that:

"Sales of long-acting insulin increased by 8% measured in Danish kroner and by 3% at CER to DKK 5,244 million. Novo Nordisk has improved its global volume market share in the long-acting insulin segment from 30.9% to 32.1% the last 12 months. Sales were driven by Tresiba® and Xultophy®, partly offset by Levemir®. Tresiba® has now been launched in 79 countries, while Xultophy® now has been launched in 32 countries" (Novo Nordisk, 2019c).

Likewise, the report informs that the International Operations Sales of insulin increased by 13% in both Danish kroner and at CER, due to the improved premix effect with long-acting, and fast-acting insulin and the increase sales of human insulin (ibid). Additionally, Novo Nordisk GLP-1 therapy for type 2 diabetes sales for (Victoza® and Ozempic®) had an increase of 18% in DKK and by 11% at CER to DKK 7,147 million. The sale was fuelled by launch of Ozempic® in 19 countries of North America Operations. The GLP-1 segment's value share of the total diabetes market increased to 15.3%, compared with 12.3% 12 months ago. These results saw Novo Nordisk continues to the global market leader of diabetes treatment with a 46.1% market share value (ibid).

Our Informant C from NN, discussed with us how the co-creation of value with patients occurred and stated that

"(...) they need to co-create value, of course when we work with the patients, we learn great deal of detail living life with this condition or this disease. But of course the people who are interacting with us they are also learn new things as well when it comes to how we develop medications, what kind of medication we have, what are the requirements from the authorities people, we have to achieve to demonstrate the benefits and the risk of the treatment, so clearly that is the role of our team to make sure that is a win-win interaction and that is not just as getting something out of the collaboration and in terms of overall objectives I mean it is like everyone these days working in that field is really to more from patients suntrik blog, lodgment and not only focusing on a medical excellence on developing a treatment, that is also making sure that the value we bring is also raising optimally with the patients" (Appendix 2).

McNichol (2013) suggests that for organizations to create value from patient involvement, there must be a good support for infrastructure and systems that respect patients at organizational level. Moreover, suitable practice guidelines and supportive systems that are easy for patients to navigate during participation process are a must. Communication systems, ease of access and even parking lots can play a key role in attracting patient involvement. In most cases, organizations lack this support system. Instead, they focus on their own structures. These are usually only designed to meet organizational needs and those of a patient. Having a complementary infrastructure system, helps to make sense and credibility for patients 'valuable opinion' (ibid).

Nicolajsen and Scupola (2011) underline that organizations utilize user involvement as a resource. They argue that if a user points out new challenges, then they co-create value by being part of the development process as a partner. The involvement is best built on confidence and abilities of the parties involved in that project and should be given the required support to co-create. Even though the practice is complex, it is important for organization's management to trust the abilities and engagement of the actors to have a success of the project.

## 4.7 Digitalization to create value

#### Digitalization at Novo Nordisk

According to Camacho and Fritsch (2012), digital transformation results in huge tangible and intangible value for all the stakeholders. Arguably, digitalization change comes with some unexpected risks and costs. It is, therefore, crucial to understand that there are some opportunities and potential challenges that come with value creation in the digital environment for different stakeholders. Digitalization evidently lowers the cost of interaction in all economic systems. Market interactions can be costly due to information exchange and organizations operations. By lowering the cost through digitalization, value creation occurs. In addition, using digitalization for the purpose of information-sharing in organization, reduces information irregularity between market participants and can result in adaptable markets with effects on competition.

Partnering with platforms such as European Medicine Agency (EMA) and EUPATI, Novo Nordisk reduces costs of interaction in patient involvement, hence value creation can occur.

The platforms have open access which allows patients to voluntarily apply to be part of the R&D following requirements listed online. EMA's framework states that, the network created for European patients' and consumers' organizations lets the Agency develop a steady platform (European Medicines Agency, 2014). The platform is directed towards a wider group in an organization across Europe who possess a variety of expertise and interests. Criteria and eligibility for selection of organizations must apply to the EMA activities. These standards are to make sure that EMA can develop a contract that is more applicable and adopted by organizations responsible for European patients and consumers in the most transparent way.

Our informant from Novo Nordisk mentions that working with such platforms helps the company to assure that there is a clear way of patients' involvement in medicine development hence avoiding conflicts and:

"that patients are involved in the development of new medication not only diabetes but medication in general and of course when you work with pharma, academic or regulators, it has a very complex system with a lot of rules and regulations, so EUPATI mission was primary to draw the lines of what kind of training and profile patients' needs to be fully equipped to have a constructive dialogues with pharmaceutical industry, academics or whoever they needs to be engage with" (Appendix 2).

Lustgarten and Colbow (2016) argue that technology adoption in healthcare and health-related industries, reduces that cost of healthcare across the world. For organizations to create value in healthcare, it is vital to change the systems to make it less complex for easy adaptation and access to all stakeholders. Technology is relevant in healthcare growth and it supports technically skilled people in raising capital for the industry. Platforms such as EMA and EUPATI help organizations like Novo Nordisk facilitate patients and consumer involvement by evaluating the benefit/risk ratio that comes with activities (European Medicines Agency, 2014). Moreover, such platforms create value for patients providing with information about the current use of medicines and living with a disease or information about lifecycle of the medicines. On the other hand, it allows for R&D and post-marketing investigation at a low cost (ibid).

Business can benefit from digital transformation because it results in increased efficiency and effectiveness for the current value chains; it rearranges them, unleashes opportunities for new value creation (Camacho and Fritsch, 2012). Technology is growing and so is competition in different ways and, therefore, all organization need to adjust to new emerging ways of digital science (ibid). Innovation rates and R&D cycles for products and services are increasing due to customer involvement and technological opportunities.

As discussed, earlier Novo Nordisk (NN) has committed to be the leader in diabetes treatment. The company continues to invest more resources into innovation, R&D and in technology to give the diabetes patients the best treatment. NN stated that in 2005, the company launched the company's brand concept Changing Diabetes® (Novo Nordisk, 2011). NN's aim is to be the world's leader in diabetes care. The company takes on the responsibility to make a difference by contributing to innovative treatments with leading initiatives to create value in the lives of people with diabetes and at risk of diabetes. The initiatives target all stakeholders (patients, healthcare professionals and policymakers) of the industry. This can be seen from the history of insulin development that has been changing over the years. With digitalization patients have the option of using a pen or a pump (ibid). Health professionals use different brands to treat patients if it meets the patient's needs. Our diabetes expert U discussed with us how brands were not a priority to patients and to them when it came to treatment. The goal is to prescribe the medicine that will make a difference in the patient's life - to cope with the disease, and noted that:

"We would do patients education on their disease and tell them about types of treatment available but not going to saying this is specific Novo Nordisk product and it is a company. From my perspective, to the patient it is unnecessary information because if it is a lilly, Novo or saniona insulin it does not matter. It is the type of insulin that best suit for the patient needs, Whether insulin or tablet that is decided for the patient and that will be patient education" (Appendix 1).

Ramsey and Seth (2017) argue that companies can benefit from incorporating patient involvement through digitalization technology. The technology has potential to utilize resources which have not been put in use yet in the care system. Professionals can reduce their work by involving patients as part of their care by asking the patients to fill in considerable information of their health record on their desktop computer or smartphone. Engaging patient health care through e-health it brind potential of generating more information that can be stored for future references giving physicians time to focus on health improvement and treatment rather than data management.

## Digitalization benefits for patients

Digitalization is not only beneficial for business, but it changes the nature of employment and lifestyles (Camacho and Fritsch, 2012). Digitalization comes with flexibility and greater work participation opportunities. It also changes lifestyles by making them much easier. And feasible alternatives to owning physical goods. Digital transformation clearly encourages greater transparency by minimizing information irregularities. The users are provided with more options in terms of accessibility to new products and/or services. This comes with better experience, as well as the convenience they need. Moreover, opportunity to access lower prices and information regarding different activities arises.

Our informant *P* clearly recognized that the insulin treatment has developed and, that digitalization has made the treatment better and easier to cope with everyday life. He stated the he was using a pump called Tandem T: slim X2 from rubinmedical.dk which he finds to be easy to use and convenient. He stated that,

"I have needle in my stomach and the pump is connected into my tummy, when I eat I count the hydrates and tell the pump and take my blood sugar that tells me how much insulin I have to take "(Appendix 3).

#### Tandem T: slim X



Figure 10. Pump, *Tandem T:slim X* (https://rubinmedical.dk)

According to (rubinmedical.dk, n.d.), Tandem T: slim X2 pump grants patients with flexibility and greater management of blood glucose control. It proves to be easier to manage comparing to pen insulin. The pump allows the patients to actively track their blood sugar levels and adjust their insulin doses all the time as needed. Patients are empowered to take an extra step towards improved comfort of life with better management of the disease. The insulin pump, however, does not work automatically to treat diabetes. Instead, patients need to *tell* the pump what do by entering the required data.

Our informant *P*, found it convenient and the best possible solution to his everyday problems with diabetes,

"I have needle in my stomach and the pump is connected into my tummy, when I eat, I count the hydrates and tell the pump and take my blood sugar that tells me how much insulin I have to take." (Appendix 3)

Health wearables technology plays key role in the preventing health-related risks (Lustgarten and Colbow, 2016). Digital wearables health devices for diabetes or blood pressure control, are, for example, equipped with sensors that record live data and transmit it via an app to the health professionals (ibid). This results in better management of the disease for both parties. The technology improves patient's management of their well-being by allowing them to analyze data for an entire day. Consequently, it amounts in the necessity for less doctor's visits.

*P* stated the he only goes to the hospital after every 3 months because he manages the disease at home. In *P*'s own words:

"(...) after every 3 or 4 months I go to hospital and they take my blood pressure, they take a lot of blood from me and control if there is something wrong, they check my eyes, my kidneys and my everything (...) If I have some question, of course I can call them and will say there is something that I don't know, if you can help me and they do" (Appendix 3).

Digitalization in healthcare, provides an individual with "custom-made" health management "programme" that includes prevention of risks. Evidently pharmaceutical industry is making progress in developing medicine in simple terms to suit individual patient's needs (Lustgarten and Colbow, 2016).

Marko-Holguin *et al.*, (2019) say that using Short Message Service Technology allows patients to be actively involved in their health care which can result in improved health with lower health care costs. Patients with chronic medical conditions (CMCs) require high involvement of health professional. It often requires a complex treatment plan. However, with digitalization the additional hospital visits are prevented.

Digitalization has played a vital role in digital health care where we have seen the rise in electronic health and mobile health (mHealth). It brings opportunities to give patients a better approach to involvement in a cost-effective system. Moreover, communication support of treatment, encourages patients to be more committed to their health (ibid). Using text messaging technology - (SMS) short message service, in health has benefits of lowering communication cost. Texting technology is widely used as a source of value creation by people of different socioeconomic backgrounds, cultures and ages. This digitalization technology is used on different platforms with no effort or skills needed, and at low-cost. Likewise, many families with low-income can benefit

from it, because texting technology brings an opportunity of to engage with patients as they are connected to their everyday life. The society takes advantage from digital transformations as well. It creates value due to more efficient and effective public administration procedures of services in health care and coping with the aging population (ibid).

According to Endev (2013) having patient-driven digital health gives patient a committed core solution of high-quality healthcare. Digital health brings structure that is able to meet each individual's needs and wants by improving the communication, resulting in effective exchange of information in the healthcare system. The system collects data and assists health professionals in prioritizing what is important regarding clinical visit for patients.

## 4.8 Knowledge for value creation

Ramsey and Seth (2017) argue that the health care system is without a doubt gradually adopting multidisciplinary care terms. This includes home care medical practice as well.

To achieve this, a good technology to facilitate communication is required. The systems enhance relations and interactions between a patient and their physician. It also improves the interaction care team-patient, and physician-team.

Open access allows patients to actively participate in their own health record and integration of the workflow in the healthcare environment. There are different approaches to the way patients can access information on their health. Knowledge is a key resource for all organizations in the R&D. Novo Nordisk (NN) acknowledge the importance of it and use different platforms to gather information on product and service improvement or development.

Disease Experience Expert Panels (DEEPs) is one of the systems used to share knowledge and engage patients (novonordisk.n.d.). NN states that it is where the company's Global Patient Relations team puts the approach of patient-centred approach into practice. DEEPs are collectives of different individuals living with chronic diseases. The individuals, their families and health care professionals can give insight on information related to a specific disease and advice based on experiences of their own. Panels are recruited across four therapy areas of the company which are: type 1 diabetes, type 2 diabetes, obesity, non-alcoholic steatohepatitis (NASH) and atherosclerotic cardiovascular disease (CVD) (ibid). DEEPs members mentioned above and their advocates who

give expert knowledge and understanding of the needs and challenges of living with chronic disease. These inputs provide NN with the insight to develop a guide model to its care delivery and guide the company's R&D for better innovative treatment of the disease. The Global Patient Relations team works with DEEPs members on a range of different projects, including advisory boards, workshops, interviews and presentations. The image below presents four types of DEEPs membership used by Novo Nordisk.

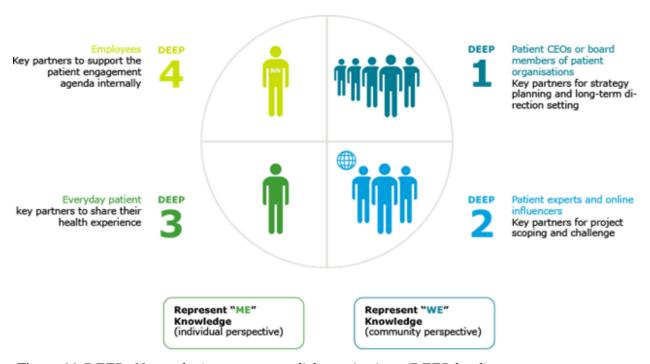


Figure 11 DEEPs Networks (www.novonordisk.com/patients/DEEP.html)

NN's DEEPs programme is based on the belief that when people share experiences, the company listens and learns how to improve lives (principle of "listen and learn"). The programme provides a platform where individuals with specific chronic disease can be involved. This involvement is based on sharing their valuable knowledge and experiences, which contributes to improvement and empowerment of individuals lives with similar diseases (ibid). The DEEPs initiative is thought to have empowered the company to design or improve clinical trials. It also helped unleash development of effective support system materials to deliver more involvement in awareness of the diseases campaigns (ibid).

Our informant from NN underlined that DEEPs and other initiatives from NN, have partnered in global advocacy projects such as EUPATI for the benefit of company and relevant patient communities:

"So if you go on the website of EUPATI you will see that they have put a lot of definitions of what profile of patients you can find out there, what the role of patient should do when they are in dialogue with the pharmaceutical industry, because Novo Nordisk is key contributor to EUPATI, we have for most of the recommendations that comes of EUPATI we have to apply them in house. So from our work with EUPATI we started to create our own network of patients that we call DEEP (Disease Experience Expert Panel) and also as the suggestion of the EUPATI we have developed kind of theory of the patient because patients comes with different kinds of expertise and experience with their own disease" (Appendix 2).

Attracting a pool of patients who can act as experts in their disease and its treatment creates quick and efficient way for organization and agencies to identify the right patients for involvement in product-related activities, information and communication material reviews (European Medicines Agency, 2014). Interaction between the network of European patients' and consumers' organizations have the potential of creating valuable contribution in knowledge that can support the existing structures for information distribution within the actors. The interactions between the networks, promotes knowledge creation and empowerment to both actors. The programme is supported by customized one-to-one support for individuals involved in specific activities. Through these activities, patients are empowered to act as recognized advocacy actors at European level.

It is important for organizations to define their end-users' needs and develop a technology based on meeting and satisfying those needs (Marko-Holguin *et al.*, 2019). Having a structure allowing to interact closely with the end-users, especially in health care, can lead to a successful R&D. Patients advocacy, experienced experts in the disease, licensed clinicians and research professionals, play a key role in narrowing down the definition of the patients' needs and can provide better way to assess the technology and how.

Our informant U, the expert from the diabetes centre, describe how they manage patients' information that is available on different platform. Their duty is to advise patients by verifying the information based on the knowledge they know about the disease and stated that;

"Actually, I think it is your privilege if your patients are curious and want to seek more information and of course you will have a discussion with them is this a valid information or is it not valid information. The department that I run is next month launching a central online knowledge where the knowledge is specific in the way that its document is valid, it is solid out, the evidence comes from a well reputed institution. So, we know what we write there is correct, it is something that can be trusted. But there is a lot of time Yes, the patient will reach something they will come. If I am lucky and have a good relationship with my patient, they will come and ask me this is right doctor and I can say yes or no and we can have a debate or discussion about it and also where to seek information that is valid compare to that is not valid." (Appendix 1).

According to McNichol (2013), organizations create and develop knowledge to make life better for individuals wearing personal health gadgets for their chronic disease's management. By this, patients can focus on finding which product and service they believe meets their needs best.

There are different open platforms, where patient as a consumer can get knowledge and can choose how to use, access, and buy services and products if it makes their lives better. Using direct observation and understanding what people want, organizations can design a product for that need. For instance, our patient informant P, shared with us that he had observed other patients using a certain pump. The pump made their life easier compared to the one he had been using. "P" decided to ask his doctor to change to that particular pump. As P described it:

P: "I saw people have it, many years ago I saw people have it, but I thought it was only for young people, so many young people about children 15, 20, 25 years old I saw many of them had a pump, so I thought it is not for me, then I asked the doctor at Novo hospital, he said: of course you can have a pump if you want" (Appendix 3).

EUPATI community encourages patients to use webinars because it provides with them some benefits such as:

- shortening time for development of ideas because it is easy to know what the majority wants,

- it is patients friendly,
- it has quick recruitment process with less dropouts from the programme because the patients are well informed before getting involved (EUPATI, 2018).

Through webinars, the health care system acquires knowledge of real-life experiences. Moreover, it gains social accountability from the users in the industry and the disease environment which can result in quality improvement approval and increase in market access making it a win-win situation.

Our informant C from Novo Nordisk backed the above statements and expressed that

"But of course the people who are interacting with us they are also learn new things as well when it comes to how we develop medications, what kind of medication we have, what are the requirements from the authorities people, we have to achieve to demonstrate the benefits and the risk of the treatment, so clearly that is the role of our team to make sure that is a win-win interaction and that is not just as getting something out of the collaboration and in terms of overall objectives I mean it is like everyone these days working in that field is really to more from patients suntrik blog, lodgment and not only focusing on a medical excellence on developing a treatment, that is also making sure that the value we bring is also raising optimally with the patients" (Appendix 2).

Having a big database of information in health care, can help the industry to predict disease epidemics, develop a cure or improve quality of the treatment and prevents death (Lustgarten and Colbow, 2016). The world's population is still growing, and life expectancy is getting higher in many parts of the world. These changes are occurring in the model of how treatment is delivered, and most decisions are made based on this data collection of new research in healthcare industry. There are different types of data collection. These include medical records and traditional clinical trials as well as new research and user-generated, that are beneficial to all parties involved. In today's health care, it is argued that patient's interaction'. creates new data towards health care model that provides with untapped opportunity for R&D.

## **Conclusions**

This section of the thesis sums up the entire research study. Going back to the core objective of this study, the previous section has given us an extensive understanding of the necessity of user-driven innovation in the company's production process. Using Novo Nordisk as our case study, we have seen how user-driven innovation is embedded in the big corporation's business strategy. Being highly cautious of varying factors that influence business operations, the results of this study remain valid within this context and cannot be generalized outside the scope of this study.

Innovation is an action which brings out a new product or function, it is a key element for the growth of an organization and also provides a competitive edge for companies in many liberal markets which are susceptible to competition. Due to the stiff competition, providing optimum customer satisfaction is a key priority to maintaining a customer base and more or less carving a niche. Hence the necessity for companies to integrate UDI in their business operations.

The User-driven innovation idea first came to academic circles and latter in 2005. For the first time, the purchaser has an integral role in product production. As noted in the literature review section of this paper, User-Driven Innovation could be in diverse forms of feedback and support systems.

Novo Nordisk is a global healthcare company with over 85 years of innovation and leadership in diabetes care. The company is also a leader in hemophilia care, growth hormone therapy, and hormone replacement therapy. Novo Nordisk's headquarter in Denmark the company employs more than 30,000 employees in 76 countries and markets its products in 179 countries. As a leading industry player, it is their objective to stay ahead of the flock of competitors by ensuring that their products meet the needs of their customers. For this reason, they involve their customers in every step of the production journey. From the interviews we conducted, it is evident that they perceive that their customers are experts in determining how well their products are rather than their inhouse technicians and chemists.

Prior to this research, our knowledge about diabetes care was limited to insulins. Surprisingly there are a plethora of other intervention drugs for diabetes as discussed in the literature review section

of this research. This changed the cause of this research, we began the research by investigating the role of customers in the development of insulin, however, since we discovered there is more to it than insulin, our research question changed to; How has Novo Nordisk used the concept of user involvement in R&D? In the quest to find answers to this question, we conducted 5 expert interviews by using a purposeful sampling technique. For the findings to be representative, we 2 of the respondents are industry experts whereas the other 3 are customers who have been using Novo Nordisk product for a long time.

Prominent in the findings of this research is that User-Driven Innovation is at the center of all the activities of Novo Nordisk. As a result, we observed that the implementation of UDI in Novo Nordisk has facilitated strong interaction and relationship between them and their customers. something that their customers were happy about.

Novo Nordisk as a giant in the pharmaceutical industry likes to consolidate its brand position as the "company that truly cares for its customers". This to some extent has worked and influenced other industries to adopt their model of operation to be customer centric as well.

One interesting finding from these studies is that, although user-driven innovation improves customer satisfaction, it is also identified as integral to pushing the frontiers of innovation by taking feedbacks and suggestions from customers. By allowing the feedback loop, Novo Nordisk is able to tap into a large pool of "free consultants" who have experience in using their drugs, suffer the pain they're trying to solve and knows the values of other competitors on the market. Such rich information further perpetuates Novo Nordisk's position in the market, since they are able to stay ahead of innovation and talk to the needs of their customers. This customer-centric approach has sprouted to be the model of operation for many industry players as well.

The EUPATI developed guidance documents for all stakeholders who aim to interact with patients on their medicines R&D.

The guidelines are in four separate documents for patient's involvement, which are as below: Pharmaceutical industry-led medicines R&D. it contains a research priorities, b research design and planning, c research conduct and operations, d dissemination, communication, and post-approval.

Ethics committees. It includes a trail concept phase, b. Trail design phase, c ethical review by research committees, d after the end of the trail.

Regulatory authorities.it focuses on, a. pre-submission, b. evaluation, and c. post-authorization.

Novo Nordisk uses the European Medicines Agency (EMA) guideline. It is the guideline of interaction among the patients and medicines regulatory authorities. The regulatory authorities are both national competent authorities and the European Medicines. The main purpose of this guideline is assisting the regulators to access real-life experiences of diseases and get the current information about the use of medicine to become able to manage the disease in a better way.

The HTA process gives information about the development, use of health technology and the beneficiaries; likewise, it assesses the benefits and the risk of the medicine.

The Novo Nordisk by the help of HTA involving the patients in their R&D process and it is still developing.

Involvement of patients is much important in the treatment process because they are living with a certain disease for a long time, so their experience becomes almost the same as an expert in the field.

To involve the patients in research and development (R&D) process give an opportunity for the Novo Nordisk to design and produce medicine according to patients needs and wants.

Patient's involvement is important for the health improvement because by patient's involvement the organization can improve the quality and the competency.

Involvement of patient in the innovation process can help the pharmaceutical companies to recognize new market opportunities; likewise, it can determine the demand for a new product or improve an existing product, that results in competitive advantages and leading the market.

In 2018, the Novo Nordisk restructured its R&D department to accelerate the diversification and expand its pipeline and to enhance investment in transformational biological and technological innovation. As a result, the company increased its sale and market share globally, therefore, Novo Nordisk became the leader of diabetes treatment in the global market by having a 46.1% market share.

The respondent from Novo Nordisk mentioned in her interview that "when we are developing new medication we have a discussion with the patients, so, it is win-win interaction it means that both parties are learning something, in this way the patients are co-creating the value. It is also mentionable that the value, which we are bringing, is according to the demands of the patients."

She further reveals that the involvement of the patient in their UDI feedback system is based on the patient's confidence and abilities, however, the process is complex but in order to co-create value and have a successful project, the company is doing it.

Technology plays a significant role at Novo Nordisk in terms of patient's interaction and value creation. The company is using the EMA and EUPATI platforms for patient's interaction and value creation. These platforms have open access and the patients can voluntarily take part in R&D after fulfilling the online requirement and eligibilities. The respondent from Novo Nordisk mentions that by working with these platforms the company makes sure that there is a clear way of patient's involvement in medicine development. Technology can also help the professional to reduce their work by involving the patients in filling of their health record digitally.

Novo Nordisk has Disease Experience Expert Panels (DEEPs) system that shares knowledge and engages the patients, DEEPs is a group of different individuals living with chronic disease, families and health cares who can give an insight of information on specific disease and advice based on the experiences of their own.

By the help of these inputs, the company can guide its R&D department in innovation processes to provide better treatment of the diseases.

Finally, we can say that DEEPs is empowering the company to design and develop clinical trials and unleash development of effective support system materials to deliver more involvement in awareness of the diseases campaigns.

Drawing on the data analysis and literature review, this research can confidently argue that Novo Nordisk employs a technology-assisted feedback system that allows customers to give feedback at every stage of their production and innovation process. This is one of the key reasons why Novo Nordisk remains the industry leader in diabetes care.

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# **Appendix**

## Interview guide.

#### **Interview Questions for the experts**

- 1. Is the concept of user driven innovation relate to your organization and how is it used?
- 2. Are there any programs that involve user in diabetes treatment development?
  - A. Are there any programs that involve user in diabetes treatment development?
  - B. What is the approach for knowledge? In/out? Out/in?
- 3. What are the opportunities and challenges of involving user?
- 4. As a professional person in this field what points should Novo Nordisk keep in mind in order to improve the quality of insulin?
- 5. Are there advantages of using insulin instead of tablets?
- 6. What is the mission in terms of objectives, scopes that you wanted to achieve by involving users?
- 7. As we know the quality of insulin has changed during the last 10 years as a professional what main differences you see and how they should improve it?
- 8. As we know the quality of insulin has changed during the last 10 years as a professional what main differences you see and how they should improve it?

#### **Interview Questions for the patients.**

- 1. Can you please tell us what type of diabetes you have and how it was diagnosed?
- 2. For how long have you had diabetes?
- 3. What type of medicine do you take in terms of insulin and tablets? What type of insulin
- 4. Following the above question how did you decide on the type of treatment? (interested to know the management and convenience of the decision)
- 5. Are you using particular brand and why so?
- 6. How well do you know the brand?
- 7. Are you part of a programme in that particular brand?
- 8. If yes how and what is your role?
- 9. How much are you involved in your treatment? Do you have a say on how you want to manage it?
- 10. How often do you see your doctor and how often are you in dialogue with s/he?
- 11. How do you come aware of new product?

## Appendix 1 2 3 4 5 attachements.