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## New Open Scenarios for STAT-ON™: The Business Perspective

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### **Abstract**

This chapter provides a general overview on the open new business perspective when using the appropriate technology to implement new eHealth services and consultations. By focusing on Parkinson's disease only, this chapter will encompass the incidence of PD, the importance of patient-centered care, how it can benefit from technologies, the market size, and opportunities at the healthcare ecosystem level. Finally, different use cases and STAT-ON™ applications are presented where relevant. Given the clear lack in the clinical evaluation of PD, we conclude that a global claim for technologies is recognized. Furthermore, given its extended scientific backup, including key validation studies, STAT-ON™ can be considered as the new gold standard for PD evaluation.

### **8.1 Introduction: A General Overview**

The incidence of Parkinson's disease (PD) in our society is significant and is growing exponentially. About 8.5 million people worldwide have been diagnosed according to WHO, a neurodegenerative disorder with disabling effects on its sufferers and with no cure. Only in Europe, there are 1.2M patients, according to Parkinson's Europe Association.

The prevalence of the disease ranges from 41 people per 100,000 in the fourth decade of life to more than 1900 people per 100,000 among those 80 and older [1]. It is expected to double in 2040 or even triple, assuming other

factors than aging [2]. PD is the second neurodegenerative disease around the world after Alzheimer's disease. The incidence of the disease has an estimated 4% of people diagnosed before the age of 50 [3], and PD has a high impact on life duration expectations and Quality of Life (QoL) for all the persons affected by it.

In daily clinical practice, healthcare professionals, patients, and caregivers have a hard time to make a complete and objective clinical assessment of PD patients. Due to high costs and major time spent, usually, patients are examined once or twice a year with a relatively brief clinical evaluation. When treating PD, neurologists use a methodology to evaluate the disease progression mainly based on a report filled out during the patient's visit. Also, patients tend to show up to the visit post to medication intake, which leads to difficulties presenting real symptoms of the OFF state of the patient while in front of the doctor. Moreover, the "white coat effect" and the "Hawthorne effect," intended as the behavioral change due to the awareness of the patient of being evaluated, affect the severity of the symptoms presented during the doctor's visit.

Furthermore, for remote symptomatology monitoring, healthcare professionals must rely on patients' diaries, which patients often have reduced compliance to, and major recall bias. In addition, the current procedure often leads to a subjective evaluation and a lack of information in the doctor's office to properly evaluate the PD patient. Thus, there is a big claim for more objective measurements in order to provide more home-environment information and daily life symptoms and achieve a more accurate diagnosis and follow-up, leading to more efficient therapy management. In this regard, **STAT-ON™ answers to these issues by overcoming the subjective and well-scientifically demonstrated difficulties with questionnaires for PD patients. STAT-ON™, in fact, provides objective information about the severity and distribution of PD motor symptoms and their fluctuations in daily life, allowing for unbiased monitoring of the patient.**

Motor fluctuations are the most perturbing symptoms, according to patients. According to the DEEP study from Stocchi et al. [4], there is an infra-diagnosis of the first fluctuations leading to providing an inappropriate therapy already from the early symptoms' detection, directly impacting QoL in further years. Given the strong symptomatic ON/OFF fluctuations and the failure to accurately track the progression of the disease by the existing standard of care, resulting in poor QoL and higher dependence on the patient.

A worse QoL impacts economics, with more hospitalizations, productivity loss, and additional care problems. PD turns into a total social cost

of €13.9B per year, meaning €11,6K for patient/year on average, including direct medical costs and loss of productivity of both sufferers and caregivers in Europe [5].

It is important to highlight that in PD, the main cost is not associated to drugs (4.4–20% depending on the analysis) but to the support and nursing that lead to €11Bn in the EU, €9200 per patient as the average of total cost of care (TCOC). However, these costs can be lowered substantially with the use of a correct technological support because STAT-ON™ can alert the physician about the real state of the patient in terms of motor state, focusing more concretely on aspects such as gait disturbances or freezing of gait (FoG), which leads to falls. Recently, it has been demonstrated that STAT-ON™ is able to detect early fluctuations and dyskinesia [6–8], leading to an appropriate titration of the patient and an accurate early therapy prescription.

## 8.2 The Use of Technology for a Patient-Centered Care

The recent COVID-19 pandemic has highlighted using technology as key for patients' remote monitoring and improving treatment and diagnostic options. The pandemic has led, in fact, to a striking evolution in the use of telehealth, intended as the variety of technologies and services to offer patient care and improve the healthcare delivery system as a whole. The scientific community has, in fact, claimed the major need for technologies for a better and more efficient clinical practice.

Within the neurodegenerative disorders field, several neurologists state that due to the rise of the burden of neurodegenerative disorders, the healthcare systems will suffer from a deficiency of basic healthcare services in the next few years. Given this scenario, a reliable tool to detect a patient's motor state objectively and remotely is key to delivering better neurodegenerative disease management. **Therefore, the appropriate technology will be essential to transform the classical PD evaluation, moving forward to a new paradigm in clinical practice.** In this regard, the STAT-ON™ Holter postulates as the best technology to achieve this goal, given its characteristics, clinical validation, and scientific endorsement.

In PD, there is a clear need for new methods to permanently track PD symptoms and improve PD patient's state to properly care for them diminishing nursing and medical costs. STAT-ON™ is a clear empowering tool for patients, which allows to track and send remotely reliable and objective information in home environments, which physicians would otherwise obtain incorrectly in ambulatory conditions.

As a consequence, the integration of STAT-ON™ in telehealth and telemedicine will allow for better and more efficient remote monitoring, improved therapy, improved assessment, and improved disease management as a whole, in clinics, home healthcare, as well as in both public and private hospitals.

In this regard, in the past decade, the concept of healthcare has moved from a clinician-centered vision to patient-centered care. The latter refers as the practice in which patients actively participate in their own medical treatment in close collaboration with their healthcare professionals for better patients' outcomes. Among its key pillars is access to medical information and education on specific diseases, as well as easing access to care. STAT-ON™'s reports, comprising weekly graphs, reporting patients' symptomatology patterns, and specific tailored variables on patients' gait with personal set thresholds, allow the patient better to understand their key symptoms and fluctuations throughout the day. In this way, the healthcare professional can educate their patients about their disease stage and progression, making them feel part of their therapy and therapeutic adjustments.

Improvements in therapy adjustments, in fact, lead to improved patients' QoL, and, therefore, to improved healthcare professional–patient relationship. Moreover, STAT-ON™, when integrated into telehealth and telemedicine, allows patients to have better access to more personalized care through technology. STAT-ON™, in fact, enables continuing access to the improvement of patients' care thanks to its data and tailored analytics. Furthermore, the usability of technology, especially for body-worn devices, is essential, and it is crucial to ease the setting of the sensors to maintain the adherence of the patient to the technology. Usability needs to be tailored to the patient and can be considered under different perspectives: ease of use, number of sensors, and part of the body where the sensor or sensors are located. It is well known that, if the system implies wearing more sensors, the precision may be higher for a more variety of movements, but user satisfaction and experience drop drastically. In this regard, **STAT-ON™ has been demonstrated to score high on usability** thanks to its comfortable belt which allows the patient to wear it in home environments.

Thus, it can be claimed that telehealth will provide key benefits both at the individual level and the healthcare system level. Major benefits have been identified, among which:

- programmed clinical monitorizations,

- annual cost-saving visits due to accurate diagnosis,
- follow-up compared to routine care only,
- technological innovation introduction at a large scale in different health-care systems,
- greater accessibility to large-scale clinical data at a governmental level,
- better management and control of the disease in remote and rural areas,
- improved patients' and clinical experience thanks to better decision-making outcomes,
- reduction of disease burden for the healthcare system and the community.

### 8.3 Market Size and Impact

STAT-ON™ can be considered as part of four different but connected, rising markets (medical wearables devices, telemedicine, Parkinson's disease, and artificial intelligence). As mentioned in the previous chapters, STAT-ON™ is a wearable medical device aimed at monitoring motor symptoms of PD. It is based on artificial intelligence algorithms and could be used to monitor a patient remotely.

The market of medical technologies, more concretely of wearable medical devices, is a rising market that enables physicians to get voluminous patient data in real environments, allowing them to perform more accurate evaluations. The Compound Annual Growth Rate (CAGR) is estimated to be 20.5% in 5 years, and the expected market size in 2026 is \$46Bn.

The COVID-19 pandemic, among other socioeconomic and technological factors, has led to accelerated adoption of new technologies to support healthcare professionals and even replace some of the methodologies used in the last decades. In the case of Parkinson's disease, patients have decreased the number of visits but worsening their symptoms at not being well treated. This, along with the advance of Internet of Things - IoT devices, telehealth apps, virtual hospitals, made healthcare API market and telemedicine growth faster in the last years. The global market size in 2030 is estimated at \$310Bn with a CAGR of 3.56% from 2020 to 2028.

Parkinson's disease global drug market forecast in 2028 is expected to be \$12.3Bn with a CAGR of 12.3 over 2022 and 2028. It is a rising market, as patients are forecasted to double in 2040 compared to numbers in 2022. According to many presentations in the Movement Disorders Society event MDS2021, there is a clear need to detect patients earlier in each one

of the stages of Parkinson's disease in order to provide them with a correct and tailored therapy. Pharmaceutical companies are competing between them to situate their drug solution in a specific stage of Parkinson's disease. However, the main issue comes in the evaluation of the patient, which continues to be problematic, subjective, and with few information about the real state of the patient. STAT-ON™ will help the physicians in the decision-making process and will allow to detect a patient earlier for a concrete treatment or therapy improvement (as an example, see a collection of real cases in Chapter 6).

Finally, artificial intelligence is a growing market. With the advent of machine learning techniques, deep learning, and big data, artificial intelligence will gain more importance in the coming years. The CAGR is 38.1% from 2022 to 2030, and the market size, although there are many different conclusions and results, it is estimated to be \$1,591Bn by 2030<sup>1</sup>.

The global medical devices reimbursement market was at \$427Bn in 2021 and is expected to reach over \$860Bn by 2030, with a Compound Annual Growth Rate (CAGR) estimated at 8.1% in this period.

## **8.4 STAT-ON™: The New Gold Standard**

When discussing the competitive landscape, it is convenient to consider the existing medical devices, among which is STAT-ON™. Other technologies, not certified as medical devices, claim that they are valid solutions, although only the certification process can guarantee the characteristics of accuracy, reliability, and safety for the patient.

Many of the existing competitive solutions to STAT-ON™ exhibit inferior characteristics, and the main reason is their location on the patient's body when they are wearing it (many of them are placed on the wrist), which means that they cannot correctly detect, with the required reliability, the symptoms that they are supposed to detect (bradykinesia, FoG, etc.). Other solutions are in different stages of technological development; however, they have not yet gone through the certification process.

A clear advantage of STAT-ON™ is its easiness of use, combined with the capacity to register with a single unique device the motor state in home-environment conditions with clinically validated advanced machine learning algorithms. As a result, the system is a single certified medical device, based on inertial technology and worn at the waist, from where PD

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<sup>1</sup> Market reports <https://www.precedenceresearch.com>

motor symptoms such as bradykinesia, gait disturbances, Freezing of Gait, or dyskinesia, can be very well detected, characterized, and registered.

The manufacturing company (Sense4Care SL) aims to establish STAT-ON™ and all its derivate devices as a gold standard for monitoring Parkinson's disease in home environments, directly impacting the evaluation of PD patients in clinical practice and during the execution of clinical trials.

The following text will present and discuss four different use cases, to open the mind to new services, business approaches, empowerment of the patients, and the establishment of new relationships between patients and their neurologists.

### **Use case 1: The case for early and advanced PD detection**

According to some discussion with different players in the field (different companies, business developers, and neurologists), one relevant conclusion is that STAT-ON™ is a considerable tool for neurologists to detect PD at each stage, and however, early PD and Advanced PD detection have been demonstrated to be the most applicable stages, and pharmaceutical and MedDev companies can benefit from STAT-ON™ to detect patients earlier.

Early PD detection can be challenging as motor fluctuation recognition is not always clear to the patients, and therefore, they cannot explain themselves properly in the clinical consultation. However, STAT-ON™ has been recently recognized as a useful tool to detect motor fluctuations, even if patients were not aware of their symptoms or did not report any kind of symptom [6, 7]. Similarly, in another study, morning akinetic patients were detected by using STAT-ON™ by analyzing the gait fluidity only [9]. Thus, as mentioned in the previous chapter, although further evidence needs to be generated, STAT-ON™ could be useful for early detection of predictable fluctuations (morning akinesia; wearing-off) and double-checking whether the patient is actually having these fluctuations or not. Moreover, as the disease progresses, STAT-ON™ can be used to monitor these fluctuations, check daily motor patterns, and predict the patient's ON and OFF states during the day. **Indeed, in the early PD stage, STAT-ON™ can be useful to provide the right and most tailored therapy possible to the patient or to make a tailored therapeutic adjustment.**

Like detecting motor fluctuations in early PD stages, STAT-ON™ can also be useful for detecting patients with advanced PD symptoms (APD) needing second-line therapy. In the DISCREPA study [10], the authors found that around 30% of APD are not well diagnosed as APD and continue taking conventional drugs that do not allow an acceptable QoL. When a patient has rated H and Y III (moderate-advanced), they reach a point where conventional

therapies are ineffective, and the only way to improve QoL is to use advanced therapies.

STAT-ON™ can monitor patients from stages I to IV. Patients with H and Y stage IV and V are considered APD. Patients from H and Y = IV represent almost 20% of patients with PD, but according to the aforementioned study, 30% are not well-diagnosed. In other words, in Spain, there are approximately 20,000 patients that can be monitored with STAT-ON™ that are in APD. From this number of patients and according to this study, there are around 6000 patients that are not well diagnosed and need a second-line therapy such as DBS, apomorphine, or duodopa infusion pumps. In France's case, 50,000 patients with a H and Y of 4 and 15,000 patients would need APD therapy. In the case of the UK, numbers are very similar to Spain.

STAT-ON™ can provide clear and objective information to detect APD patients, according to a Spanish study performed in 27 hospitals in Spain. A total of 81.5% of neurologists think that it is a very useful tool to detect APD patients, and thus, that need APD therapies by observing the time in OFF and the dyskinesia suffered by the patient in an objective way [11].

On the other hand, primary care centers (PCC) are centers where a PD patient is usually attended only in case there is very clear evidence of the condition of the patient and the impression of the generic neurologist that the patient does not respond to medication, then the patient is derived to a second or third level hospital. This process can be advanced by providing clear information (STAT-ON™ can provide it) to these nonspecialist health professionals. **The patients do not have to get to situations where their conditions are harmful, and their QoL is extremely low.** Pharmaceutical companies can be the main beneficiaries of this correct evaluation of the patients. The new evaluation and detection service, using STAT-ON™, will approach the patient to an advanced therapy when required and on time.

### **Use case 2: Better attention in public hospitals**

The main issue of a public hospital is the saturation of the health system and difficulties in managing the patients' visits. Thus, one of the main aims is to decrease this saturation, the number of visits, and the time spent out of the visits by doing reports or therapy adjustments.

An example was given by a neurologist in Barcelona, who declared that he could spend 2 hours per patient to correctly adjust a DBS system based on the information received from diaries and questionnaires. In the COVID-19 scenario, this is one of the main objectives (decrease of the saturation of the services and the minimization of the physical visits to the hospital).



Some neurologists that have widely used STAT-ON™ stand with the preliminary conclusion that **although STAT-ON™ does not reduce the time of visit, a significant improvement in the visit quality can be noted.** When the neurologist gains some experience with the use of STAT-ON™, they claim that the sensor could speed up the visit. They also state that providing the correct therapy might reduce the number of visits per patient as the therapy is correct, and patient does not need to come with such frequency to correct the therapy provided.

In this term, a new paradigm needs to be set in the public system. The sensor can be sent to the PD patient's home, and then remote monitoring can be performed. The neurologists can call the patient to perform a follow-up. This process would prevent the patient from mobilizing to the hospital. Also, management can be performed remotely and with very good and precise objective information.

This new paradigm contributes innovation to hospitals benefiting from funded projects and distinction as reference hospitals. Rigorous conclusions must be analyzed in these studies that are being performed to set up a profitable business model. **Quality of life improvement of patients is not the unique and main goal from hospitals as stated some interviewed neurologists, and costs and time are of great interest for hospital managers.**

### Use case 3: Clinical trials

A clinical trial is a very important part for the development of new treatments, performed by international research groups or by the principal pharmaceutical companies.

In a clinical trial, several control processes must be taken from the analysis of patients. For example, complex but subjective questionnaires or diaries must be obtained after filled-in with a costly supervision process for the quality of these data. In a clinical trial, which is normally funded by public entities or pharmaceutical companies, there are some key points to minimize: **the time and cost of these processes.**

The main target for reducing time and cost is all the activities performed over a PD patient out of the visit. For example, interpreting diaries, controlling the process (calls or visits to patient's home), and checking if the diary was correct or should be repeated. All these processes are cumbersome and, as reported by the PI of a clinical trial performed with STAT-ON™, diaries must be repeated several times, and it is difficult to have clear and reliable annotations. It is well known that not many patients can efficiently fill their diaries properly. Thus, the sensor can cover all patients, and there is no need to precisely control patients to fill diaries properly. The Madrid's

Parkinson's Association, in Spain, has recognized that STAT-ON™ can perfectly substitute the diary process as standardize all the metrics filled in a diary, and the information is always objective and real. Also, in a study conducted by Santos et al. with 27 movement disorders experts, 70.3% stated that STAT-ON™ was better than a diary only by having used once [11]. Diaries have the issue of reduced compliance and recall bias.

The UPDRS is the most common questionnaire used in clinical practice. It takes about 10 minutes to be filled out. The questionnaire is quite subjective, but most neurological community has standardized and accepted it. Adding the time for interpretation, digitalizing it, and making decisions, take time to the neurologist, approximately 1 hour per patient. The sensor offers most of the information provided by UPDRS on motor symptoms, reducing the time of filling and digitalizing it. Also, it provides objective information.

The time to understand the STAT-ON™ report is about 15 minutes. For clinical trials, the longer version of UPDRS is used (the UPDRS-MDS), which can take about 30 minutes to complete the questionnaire. The use of STAT-ON™ makes it not necessary to spend time filling in diaries and reduces the time spent interpreting the results of the analysis.

The possible outcomes of this process are: it is not necessary the participation of so many health professionals in a PD study, reducing the time of visits, the time of interpretation, and digitalization of diaries. However, the idea is to increase the PD patients to perform studies with more data consistency. The same staff could perform approximately the double of databases by using a sensor. Moreover, all pilots would gather objective data from the sensor and also in real-life conditions, being very productive to a pharma company as they could show their medication used in real-life conditions.

#### **Use case 4: Improvement of the service in private clinics and home-health-care centers**

These specific centers normally integrate a service with different departments (neurology, physiotherapy, psychology, etc.), offering a global health and care service to PD patients. These centers compete with others to attract patients to their services, by offering a better service which can be translated as a significant improvement in QoL.

According to the personal experience of two neurologists working in different private centers, there are two key points to analyze: **the reimbursement policy, the quality of the visit, and the service offered to the patient.**

It has already been shown that STAT-ON™ improves the quality of visit, offering a better treatment and enhancing QoL. However, additional considerations should be made for adding new quality services, based on the

use of the technology, and investigating how these initiatives would be made profitable as part of the day-by-day clinical praxis.

This case can be generalized to home healthcare (HHC) in many countries (France, in particular), where different HHC service providers have been detected, and a business model based on the massive use of STAT-ON™ must be found.

The center can empower the patient by offering him an extra service with STAT-ON™. They can also provide a STAT-ON™ to the patient, who can pay monthly rent or fee.

STAT-ON™ provides different advantages that a private center can benefit, as an improvement in therapy adjustment, which means improvement in QoL, satisfying the patient, and increasing the quality of the relationship between the neurologist and the patient. Also, the center can attend to more patients as professionals will have digital tools to evaluate objectively without doing classical evaluations such as diaries or questionnaires.

According to the previous statement, the patient can also have more visits if they note a decrease in the therapeutic effect. They will not have to wait 6–8 months. Finally, it adds innovation and added value to the offered service and offers the possible implementation of the automatic generation of alarms when some previously established thresholds are reached by specific parameters or combinations of parameters.

## 8.5 Conclusions

There are several drawbacks in the current evaluation of PD, and various studies claim the use of new technologies to provide useful, objective, and clear information of PD patients in home environments. Several patients and also neurologists enter a continuous loop where the therapy is not well adjusted, the QoL of the patient decreases, and they need another visit. The use of new technologies would offer this information, and thus, therapies could be more accurate.

STAT-ON™ is a medical device, class IIa, that acts as a real Holter for the motor symptoms of PD patients, with a high rate of usability. There are several advantages to STAT-ON™ use, and it should be a cost-effective solution for many stakeholders.

On the one hand, companies that manufacture second-line therapies can benefit from the fact that STAT-ON™ can be used to detect advanced patients. Given that there is a high rate of patients not well-diagnosed with APD, detecting these patients would lead to an increase in the use of these therapies. This fact involves two main advantages: an increase in QoL for

the patient and an economic benefit for the pharma that manufactures the advanced therapy. The same happens with first fluctuations and the need to prescribe dopaminergic inhibitors at the right moment. STAT-ON™ has demonstrated to clearly identify first motor fluctuations and the need to complement the levodopa-based therapies for reducing the time in OFF.

Also, the STAT-ON™ can help to manage better clinical trials by providing faster, more reliable, and objective information of the state of the patient, reducing the cost drastically, and speeding up the clinical trials.

In the field of hospitals, STAT-ON™ is also useful for decreasing the number of face-to-face visits (even eliminating them by remote monitoring with the sensor and a telephone call) and improving the quality of the visit by providing more accurate therapy to the patient. Innovation is also a quality of excellence to consider, as well as the possibility of managing the visits remotely given a pandemic scenario as it was the COVID-19.

Finally, several advantages have been presented in home-healthcare centers and private clinics, given that STAT-ON™ enhances the expertise and aptitudes of the center against other competitors and attracts more customers.

**In conclusion, STAT-ON™ has been presented as a perfect tool for health professionals, as an instrument that can be used to improve QoL of patients (benefiting the health systems by reducing medical care, and hospitalization admissions), and as an attractive device for pharmaceutical companies.**

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