Proposal template Part B: technical description

THE RGS ECOSYSTEM

Participant No.	Participant organization name	Country
1 (Coordinator)	EODYNE SYSTEMS	SPAIN

Which EIC topic do you want to apply for?

☒ EIC Accelerator Open

Fast Track Scheme to the EIC Accelerator

This project was submitted through the Fast Track Scheme, supported by the EIT Health, and had direct access to the Step 2 (full proposal) of the EIC Accelerator. The award criteria were equivalent to the ones set out for the 'short application stage' of the EIC Accelerator in compliance with Horizon Europe legislation.

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EXECUTIVE SUMMARY

Health services are undergoing a shift towards a treatment continuum that extends from clinical settings to the home environment. To ensure the success of this transition, which significantly impacts patient outcomes and healthcare costs, it is crucial to deploy affordable and reliable AI-enhanced technologies that can process data, provide accurate diagnostics and prognostics, and deliver personalized interventions trusted by both clinicians and patients. However, the current reliance on human expert opinion for diagnoses and prognoses based on isolated medical controls is prone to error, especially considering the high variability of recovery dynamics and the challenges of predicting post-stroke outcomes. Additionally, there is a need to support patients in a more integrated and comprehensive manner, providing sufficient treatment and addressing fragmented care systems, the lack of continued support, and the burden on informal caregivers to optimize outcomes and minimize total cost of care.

As a result of these unsolved challenges, about half of all stroke survivors present post-stroke hemiparesis, dementia, or post-stroke cognitive impairment, several specific and diffuse cognitive disabilities related to memory, attention, emotional states, orientation, and language. These disabilities lead to functional limitations in instrumental Activities of Daily Living (iADLs) and low quality of life. Moreover, about 60% of patients experience chronic effects, including pain, mood disorders, and depression all of which contribute to the high cost of care for stroke patients.

Eodyne, a spin-off company of the SPECS research lab, is developing the RGS Ecosystem (RGS-E), a scientifically grounded, affordable, and scalable neurorehabilitation solution that is aligned with the patient journey. RGS-E utilizes AI and VR/AR scenarios delivered through various platforms such as PCs, smartphones, and smartwatches. It offers gamified training activities targeting different aspects of rehabilitation, including motor skill, cognitive function, and language. The system will seamlessly accompany patients throughout their clinical pathway and at home, assuring continuity of care with personalized interventions and collecting data for diagnosis, prognosis, and clinical decision support.

Based on the CDAC theory of mind and brain, RGS-E aims to transform consumer electronics, such smartphones, and smartwatches, into tools for stroke intervention, diagnosis, and prognosis. By leveraging highly scalable devices, RGS-E will ensure the continuum of care to significantly shorten treatment at the hospital, reduce readmission rates, increase clinical staff capacity, and improve patients' outcomes. The project's work plan involves developing and refining the technological components, conducting pilot studies and clinical trials to validate the technology's clinical impact, and engaging in market studies and communication activities to refine the business plan. In the commercial stage, we will implement a hybrid commercialization model establishing sales teams in our target markets to support and manage established distributors with existing customer networks. The initial phase of commercialization will focus on Germany, France and the US, strong international markets with favorable legislation for reimbursement. In the following phases, we will scale across the EU and the US and diversify our markets expanding our target patient populations.

Overall, the RGS Ecosystem offers an effective, high-impact and scalable product that addresses the challenges of post-stroke neurorehabilitation. With its scientifically grounded approach, personalized interventions, scalable solutions, and integration of AI-based patient models for prognosis, Eodyne aims to revolutionize stroke rehabilitation by significantly reducing costs, increasing hospital capacity, and improving patient outcomes.

Part 1 – Business Case

1. COMPANY DESCRIPTION

Eodyne Systems SL (hereafter referred to as EODYNE) is a MedTech company based in Barcelona, dedicated to the development and commercialization of technology for neurorehabilitation. EODYNE was founded in 2014 as a spin-off from the SPECS Research lab, specializing in computational neuroscience and neurorehabilitation research. EODYNE follows a science-based approach and has a robust scientific track record, with over 45 publications demonstrating the clinical effectiveness of our solutions (refer to Free annex).
We have a proven history of successful research and innovation projects, collaborating with key players across Europe. This includes partnerships with reference hospitals and leading industry companies such as Medtronic, Roche Diagnostics, OSSUR, Charite University Hospital, Vall de Hebron University Hospital, Limoges University Hospital, and Sint Maartenskliniek, among many others. Notably, Eodyne is leading an EIC Transition-backed project, where the RGS-E technology has been advanced to TRL6, now completing its second year of execution. Over the past three years, Eodyne has achieved substantial success, accumulating over €3M combining grants and sales revenue and growing its team from 10 to 15 FTEs.

CORE MISSION AND VISION

EODYNE's MISSION is to deliver an effective and affordable portfolio of neurorehabilitation solutions that can address all phases of the stroke patient journey, from admission and inpatient treatment to outpatient and home-based treatment. In this way, we will ensure the continuum of care, smooth transitions in the clinical path, and leverage data to provide personalized intervention and prognosis and diagnosis tools. Ultimately EODYNE's mission is help and empower all patients in need of rehabilitation to recover as much as possible and live

healthier, happier lives while reducing the burden on healthcare facilities and workers and lowering healthcare costs.

EODYNE's VISION is to democratize access to rehabilitation, providing effective and affordable treatment to patients from all socio-economic backgrounds. We believe that drastically reducing the costs of rehabilitation is essential to allow all patients to recover to their full potential. By making rehabilitation accessible and affordable, more patients can be treated simultaneously and for longer periods than when using conventional therapies. Finally, we believe in a patient-centered approach, one in which empowered patients take charge of their recovery and the rehabilitation tools are developed and presented in a way that fulfils the patient's needs. EODYNE's VALUES are passion, excellence, innovation, and a patient-centered approach. Passion fuels our commitment to revolutionizing neurorehabilitation through science-based technology. Excellence is at the heart of everything we do. We strive for the highest standards of quality in our products, services, and research, ensuring that we deliver exceptional solutions that make a tangible difference in the lives of patients. Innovation is our driving force. We continuously push boundaries and explore new frontiers in technology to create ground-breaking solutions. By embracing innovation, we empower clinicians and patients with cutting-edge tools that enhance recovery outcomes. Above all, we are deeply committed to a patient-centered approach. We put patients at the center of our focus, understanding their unique needs and challenges.

STRATEGIC PARTNERS AND STAKEHOLDERS

To achieve our objective and ensure an outstanding commercial exploitation of the RGS Ecosystem, we rely on our extensive experience and knowledge of the market but also on a strong value chain. Our key partners and stakeholders include (Figure 1, Table 1):

Table 1: EODYNE's stakeholders and key partners for the RGS Ecosystem project

Stakeholders
END BENEFICIARIES: Stroke patients and their relatives. -**Stroke patients** directly benefit from the innovative rehabilitation solutions provided by RGS-E that help them get more and better treatment, reduce waiting times, and improve their recovery and quality of life. -**Patient relatives** also benefit from RGS-E, as it supports the rehabilitation journey with tools for self-management that increase patient autonomy, reducing the burden on informal caregivers. -**Patient associations** will promote the adoption of RGS-E to support their members, improve their quality of life, and help informal caregivers better support their relatives.
USERS: Hospitals, private clinics, doctors, patients -**Hospitals and private clinics** can integrate the RGS Ecosystem in their rehabilitation services to increase the capacity of the clinical staff, fight the shortage of trained professionals, reduce waiting times, and improve patient adherence and clinical outcomes -**Doctors and therapists** can prescribe and recommend the use of RGS solutions as part of their treatment plans to effectively treat and manage more patients.. -Additionally, as RGS-E includes several monitoring and intervention solutions that patients might use at the hospital with the therapist, or autonomously at home, patients are also end users of our technology.
DISTRIBUTORS: Companies including RGS-E in their portfolio -**Specialized companies** play a crucial role in the value chain by facilitating the distribution and sales of the RGS ecosystem products. They count with market-specific knowledge, established customer networks and normally cater to large hospitals but also small and medium private clinics that could use our products.
PAYERS: public and private entities that reimburse healthcare providers. -**Public reimbursement systems,** such as national healthcare systems or government-funded programs, can cover the costs associated with the use of the RGS ecosystem in public hospitals. -**Private reimbursement,** including private insurance companies or employer-provided healthcare plans, may provide coverage for the RGS ecosystem expenses incurred by patients in private clinics or hospitals. They directly benefit from offering more cost-effective solutions to healthcare providers and individuals, as well as costs reductions resulting from more efficiently delivered and improved care that leads to better, faster patient outcomes and fewer readmissions.
Project Key Partners
TECHNICAL PARTNERS (WP 1,2,3,4): -Saddlepoint (Tasks T3.1, T3.2, T3.3, T3.4, T4.1) provides data analysis and AI-based patient models. Their advanced algorithms and models assist in the analysis and interpretation of patient data, enhancing the effectiveness of the RGS ecosystem in personalized rehabilitation.

-Hankamp Rehab (Tasks T1.2, T1.3, T2.1) provide assistive devices that can be used in combination with the RGS-E solutions such as phone holders and anti-gravity devices for the upper limb.
MANUFACTURERS (CMO) (WP 1): Physical Equipment Manufacturers: These manufacturers supply the necessary equipment and devices that are incorporated into the RGS ecosystem, ensuring high-quality and user-friendly physical components. These might include MBIENTLAB, Maniplastic, and Microsoft.
CRO (WP5): We will count with a CRO in charge of conducting the clinical trials and ensuring the safety and efficacy of our products.
CLINICAL PARTNERS (WP 2,5): play a crucial role in clinical validation and generating the evidence for our products necessary for certification and reimbursement purposes as well as compelling selling points. We have interest from several rehabilitation centres and hospitals including the Institute of Functional Recovery La Salle (Spain), Hospital Vall d'Hebrón (Spain), and Hospital Limoges (France). (see LOIs).
BUSINESS PARTNERS (WP 6,7) To make sure we reduce time to market, reach key customers and scale commercially to successfully exploit the results of the RGS Ecosystem project, we must establish and leverage strategic partnerships with industry partners. We highlight our collaborations with Medtronic Iberica (Spain), Roche Diagnostics (Spain), Hankamp Rehab (The NL), and BrainExos (Brazil) (see LOIs)
REGULATORY AFFAIRS SPECIALISTS (WP 6,7) will help us protect our solutions and navigate the regulatory landscape and processes required to certify Eodyne's products under the MDR and to access the different European reimbursement systems. Here we will leverage the expertise of Ingecal as a key partner, with whom we have been working for the past few years.
IP SPECIALIST: will help us protect and trademark our solutions and navigate patent laws to secure patents for RGS-E, shielding it from unauthorized use.
KEY OPINION LEADERS (KOLS) (WP5, 6, 7): They will help us promote RGS System establish strong networks and partnerships and help with its commercial expansion. We count with the support of Dr. Susana Rodriguez Gonzáles, Head of Neurorehabilitation at Hospital Vall d Hebrón and Prof Stephan Mandigout, Head of HAVAE Lab (See LOIs).

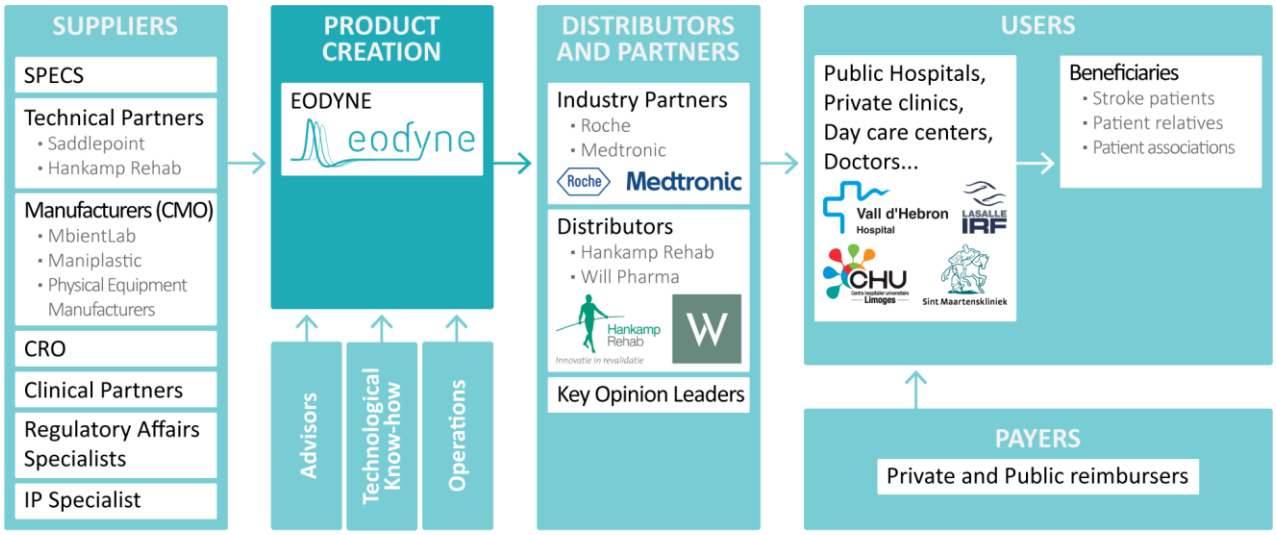

Figure 1. Eodyne's value chain

KEY COMPANY ASSETS

As mentioned above, EODYNE is a spin-off from SPECS research lab, from which we have inherited a long scientific track record and culture. Eodyne's critical assets lie in INTANGIBLE RESOURCES that contribute to the company's success. The team synergies and expertise in developing cutting-edge technologies form the foundation of Eodyne's innovation and growth. The collective knowledge and experience of the team members, many of whom have been working together for several years, enable them to tackle complex challenges in stroke rehabilitation effectively.

As such, one of our main assets is the network of hospitals, patient associations, health professionals, patients, distributors, and industry partners, established in the last nine years. Since the company creation we have engaged with distributors, technology companies, public hospitals, rehabilitation clinics, patients' associations, and patients in their own homes across several countries, including Charite University Hospital of Berlin, Uppsala University Hospital (Sweden), Limoges University Hospital (France), Hospital Sant Joan de Deu, Hospital Vall de

Hebrón, Hospital La Esperanza (Spain), Medscaler, Radboud University, Sint Maartenskliniek, Roessingh Research & Development, and Istituto Nazionale de Riposo per la Cura Anziani (Italy), among many others. Since Eodyne's incorporation, we have engaged with over 600 healthcare providers, rehabilitation professionals, and patients, including neurologists, rehabilitation doctors, occupational therapists, physiotherapists, and speech therapists, to understand the needs and pain points of end users. Finally, within our intangible assets we also count with strong software development and quality processes distilled over the last 10 years that enable Eodyne to efficiently produce high quality software and products.

Regarding its PHYSICAL FACILITIES, Eodyne's office is designed to support its activities. It counts with sixteen workstations dedicated to development and design, allowing the team to collaborate and create innovative solutions. The presence of three demonstration stations enables Eodyne to showcase our products to potential clients, partners, and stakeholders, highlighting the capabilities and benefits of their technology. To facilitate effective communication and collaboration, Eodyne has designated meeting rooms where team members can gather to discuss projects, exchange ideas, and strategize. These spaces foster creativity, teamwork, and efficient decision-making processes.
Recognizing the importance of data management and accessibility, Eodyne has invested in cloud infrastructure to ensure secure storage, easy access, and scalability of data, enabling efficient workflows and seamless collaboration across the organization.

TOP CLIENTS, SUPPLIERS, ADVISORS AND THEIR CONTRIBUTION

CLIENTS: Eodyne has successfully developed MVP versions of some of its rehabilitation solutions as standalone products that count with early adopters such as Roche Diagnostics and referent rehabilitation centers in Europe including **Hospital Vall de Hebron** (Barcelona, Spain), **Institute for Functional Recovery La Salle** (Madrid, Spain), **Brain Damage Association of Navarra -ADACE-** (Pamplona, Spain) **Centro Cerebro** (Braga, Portugal), and **Sint Maartenskliniek** (Nijmegen, The Netherlands). Moreover, **Eodyne Systems is a homologated provider to Roche Diagnostics**. Eodyne and Roche Diagnostics have signed a renewable contract from 2022 to 2024 and are looking to extend it to 2025. Moreover, we are working with OSSUR, the second biggest manufacturer of prosthetics globally, developing a solution for the rehabilitation and training of upper limb amputees. These contracts are not included in the annex due to confidentiality issues. Moreover, Eodyne collaborates with Medtronic in different European Projects and are currently working together on the development of business models to introduce AI in stroke. Importantly, in September 2023, Eodyne's CEO, Santiago Brandi, and founder, Prof. Paul Verschure, met in Bucharest with Romania's Health Minister, Prof. Dr. Alexandru Rafila, and the President of the Neurology Commission of the Romanian Ministry of Health, Prof. Dafin F. Mureșanu, who expressed interest in promoting Eodyne's highly scalable solutions to provide neurorehabilitation to the Romanian stroke population. (See LOIs).

SUPPLIERS:

SPECS lab provides scientific knowledge and research in neurorehabilitation. They contribute valuable insights and expertise to the development and improvement of the RGS ecosystem that allows us to maintain a scientific competitive edge

Saddlepoint provides data analysis and AI-based patient models. Their advanced algorithms and models assist in the analysis and interpretation of patient data, enhancing the effectiveness of the RGS ecosystem in personalized rehabilitation.

MbientLab makes sensor platforms with motion and environmental sensors including temperature, accelerometer, gyroscope, magnetometers, barometers, light and temperature sensors. It also provides MetaWear SDK that includes Bluetooth Sensor Platform, analytics and sensor based algorithms to build and scale up applications in an effective manner.

Maniplastic is specialized in the transformation of Technical Plastics through Thermoforming, Machining, Water Cutting, Laser Cutting, Handling and Boilermaking. To this wide range of technologies, they add the extensive experience and knowledge of Technical Plastic Materials and the support of the Engineering and Design Department. Maniplastic provides custom solutions to Eodyne, such as cases to integrate components.

Physical Equipment Manufacturers: These manufacturers supply the necessary equipment and devices that are incorporated into the RGS ecosystem, such as PCs., monitors, smartphone, and smartwatches, ensuring high-quality and user-friendly physical components.

ADVISORS: Central to EODYNE's philosophy of industry leadership and innovation is our commitment to collaboration. Here, we highlight the eminent professionals who not only collaborate closely with EODYNE but also play advisory roles in our projects:

Todd Snowden: Todd holds a BSc in Bioengineering and Pre-Medicine from The Catholic University of America (Washington, USA). Todd is a highly successful international healthcare executive with more than 30+ years' experience in life sciences companies. He has worked as global sales director for companies in molecular diagnostics, laboratory services, and medical devices such as Interleukin Genetics, Inc. During 2010-2013, he was CEO at PathoGene, L.L.C, a molecular diagnostics company. Currently, Todd is founder/principal of Ascent Business Advisors (Spain), a strategy consulting/interim management firm working with diagnostic, medical device and therapeutic companies in the US and EU.

Dr. Paul Verschure, Eodyne's founder and former CEO, leads the Synthetic Perceptive, Emotive and Cognitive Systems Laboratory, hosted by the Donders Institute for Brain, Cognition and Behaviour - Centre for Neuroscience, where he is a neuro-engineering professor. Paul has received his MA and Ph.D. in Psychology and pursued his research at different leading institutes in Europe and the US and manages a team of over 20 researchers and technicians with whom he has published over 400 articles in leading journals and conferences in a range of disciplines. Paul is regularly invited as a speaker at relevant scientific conferences and international policy events, a consultant for the European Commission, board member of three journals and reviews for several relevant journals and conferences. Paul is founder/Chairman of the Future Memory Foundation and founder/Chairman of the Convergent Science Network Foundation.

Per Hamid Ghatan is a medical doctor with clinical experience as a senior physician in the field of brain injury rehabilitation and occupational health medicine. He is a researcher with a PhD in cognitive neuroscience and is teaching at the Karolinska Institutet. As a medical advisor he is a leading expert in the field of brain injury prevention. Per is also a consultant with focus on organizational issues, management, leadership, team building, and has for many years conducted research into the effects of burnout on the brain. Per is part of the board of director of several health-related startups and support Eodyne on both clinical and market update matters.

Dr. Anna Mura: is a biologist with a Ph.D. in natural sciences, she has pursued her education and research in several Universities in the USA (Arizona University Tucson, University of California, San Diego) and in Europe at the University of Cagliari, Italy, and the Swiss Federal Institute of Technology-ETH Zurich where she obtained her PhD. Since 2007 she is part of the SPECS-lab first at the ETIC Department of the Universitat Pompeu Fabra in Barcelona and since 2020 at Radboud University. Anna has directed her interest on the issue of multidisciplinary education and the development of educational and research programs, scientific communication, and divulgation, and she is the co-editor of two e-books for the Convergent Science Network project and co-editor of the Living Machines conference procedures. Anna advises Eodyne on user experience design and communication and outreach activities to reach our stakeholders.

2. THE PROBLEM/MARKET OPPORTUNITY

STROKE CONSTITUTES 56% OF THE BURDEN OF NEUROLOGICAL DISEASE

Globally, 1/4 people will have a stroke in their lifetime, with over 13.7 million stroke cases each year, of which 8.2 million patients survive[1]. Currently, **more than 80 million people are living with the consequences of stroke[2]**, which include a wide range of cognitive and neuromotor impairments.

In Europe, the **total costs associated with stroke add up to 60 billion EUR per year[3]**, with non-healthcare costs such as informal care or loss of productivity estimated at 15.9 billion EUR largely driven by impairments[4]. The number of stroke survivors in Europe is projected to increase by 27%, up to 12 million by 2047[5]. At the same time, the World Health Organisation (WHO) projects a global shortage of 13 million trained health workers by 2035 and the United Nations (UN) estimates a shortage of 18 million workers by 2030.

LACK OF CONTINUED SUPPORT

The journey towards recovery includes several stages, from hospitalization to in-patient and out-patient rehabilitation and the subsequent return to home. The access to stroke units and rehabilitation varies within

[1] https://www.world-stroke.org/assets/downloads/WSO_Global_Stroke_Fact_Sheet.pdf
[2] https://www.world-stroke.org/publications-and-resources/resources/global-stroke-fact-sheet
[3] https://www.safestroke.eu/wp-content/uploads/2020/10/01.-At_What_Cost_EIOS_Factsheet.pdf
[4] https://www.safestroke.eu/wp-content/uploads/2020/06/The-Burden-Of-Stroke-In-Europe-Report-Main-Document_ENG_All-references.pdf
[5] https://www.ahajournals.org/doi/10.1161/STROKEAHA.120.029606

Europe[6], and some European patients do not have access to therapy. During the in-patient phase, daily rehabilitation sessions vary from 22 to 60 minutes[7], reducing frequency and duration at later stages[8]. The average stay at the hospital is 4.7 days, and the mean duration for in-patient treatment is 14.6 days[9]. After discharge, stroke patients might eventually lose up to 80% of the functionality re-gained at the hospital (i.e., rehabilitation in vain)[10]. The reduced use of stroke-affected limbs may lead to further loss of function, a vicious cycle of feedback between non-use and poor performance (a.k.a. use it or lose it), which leads to the previously mentioned rehabilitation in vain. This may imply that those patients responding to therapy have a bistable recovery[11]: either they do not use their affected arms and experience progressive deterioration (vicious loop), or they incorporate the affected arm into daily activities, which predicts recovery and retention of motor function (a virtuous loop where use and recovery reinforce each). Indeed, increased spontaneous use of the paretic limb facilitates practice and induces use-dependent plastic changes. This project will deploy rehabilitation technology that instils and supports the virtual cycle of recovery in the at-home setting.

Moreover, **the support of the patient is organized in a rather fragmented way**, with gaps between treatment phases and lack of continued support, while informal care places a severe burden requiring dedicated support in the patient's social environment[12]. The Stroke Action Plan for Europe (SAP-E) aims to provide Early Supported Discharge (ESD) to up to 20% of stroke survivors by 2030 which requires community rehabilitation to these patients, as well as self-management support upon discharge and routine review of the patient's status. Most traditional therapies are developed based on standard principles of knowledge, which poses the great disadvantage of needing periodic review, and are performed by humans prone to error. Besides they are not adapted to the patient's evolution. Hence, to realize the objectives of SAP-E we need to support the treatment continuum with advanced technologies.

CHALLENGES FACED BY PATIENTS

About half of all stroke survivors present post-stroke hemiparesis, dementia (PSD)[13] or post-stroke cognitive impairment (PSCI), several specific and diffuse cognitive disabilities related to memory, attention, emotional states, orientation, language understanding and production[14]. These disabilities lead to functional limitations in instrumental Activities of Daily Living (iADLs) and low quality of life, with 33,2% of patients suffering from functional dependency one year after their stroke. In addition, a third of poststroke patients display non-fluent aphasia at the chronic stage (≥6-month poststroke)[15]. Affected individuals may experience changes in language processing and learned nonuse resulting in social exclusion, depression, a compromised quality of life, as well as limited language recovery. Moreover, about 60% of patients experience chronic effects, including pain, mood disorders, and depression. Many of these patients return home relatively quickly, although they might still suffer from impairments and disabilities that require continuous rehabilitation to achieve an acceptable quality of life. Given the significant impact of these impairments on wellbeing and function and the labor-intensive rehabilitation methods, there is a need for evidence-based, cost-effective rehabilitation techniques for improving the condition of people with stroke and maximizing their self-efficacy.

HUMAN ERROR

Health services are increasingly transitioning towards a treatment continuum aligned with the patient journey, from the clinic to the home environment. However, the success of this transition critically depends on the

[6] https://www.safestroke.eu/wp-content/uploads/2020/06/The-Burden-Of-Stroke-In-Europe-Report-Main-Document_ENG_All-references.pdf

[7] Veerbeek, Janne Marieke et al. "What is the evidence for physical therapy poststroke? A systematic review and meta-analysis." PloS one vol. 9,2 e87987. 4 Feb. 2014, doi:10.1371/journal.pone.0087987

[8] Schaechter, Judith D. "Motor rehabilitation and brain plasticity after hemiparetic stroke." *Progress in neurobiology* vol. 73,1 (2004): 61-72. doi:10.1016/j.pneurobio.2004.04.001

[9] Benjamin, Emelia J et al. "Heart Disease and Stroke Statistics-2019 Update: A Report From the American Heart Association." Circulation vol. 139,10 (2019): e56-e528. doi:10.1161/CIR.0000000000000659

[10] Souza, Wagner H., et al. "Effect of a Rehabilitation Program Using Virtual Reality for Balance and Functionality of Chronic Stroke Patients." Motriz: Revista de Educação Física, vol. 21, 2015, pp. 237-243. doi:10.1590/S1980-65742015000300003.

[11] Han, Cheol E et al. "Stroke rehabilitation reaches a threshold." *PLoS computational biology* vol. 4,8 e1000133. 22 Aug. 2008, doi:10.1371/journal.pcbi.1000133

[12] https://www.sciedupress.com/journal/index.php/cns/article/view/6564

[13] Mijajlović, Milija D et al. "Post-stroke dementia - a comprehensive review." *BMC medicine* vol. 15,1 11. 18 Jan. 2017, doi:10.1186/s12916-017-0779-7

[14] Aam, Stina et al. "Post-stroke Cognitive Impairment-Impact of Follow-Up Time and Stroke Subtype on Severity and Cognitive Profile: The Nor-COAST Study." *Frontiers in neurology* vol. 11 699. 17 Jul. 2020, doi:10.3389/fneur.2020.00699

[15] Grechuta, Klaudia et al. "Augmented Dyadic Therapy Boosts Recovery of Language Function in Patients With Nonfluent Aphasia." *Stroke* vol. 50,5 (2019): 1270-1274. doi:10.1161/STROKEAHA.118.023729

deployment of trustworthy AI-enhanced technologies for data processing, diagnostics, prognostics, and patient-tailored interventions that are accurate, secure, and trusted by clinicians and patients alike. Currently, **diagnoses and prognoses rely on human expert opinion based on isolated medical controls. However, human subjective assessments are prone to error**, and predicting the outcome of interventions post-stroke based on the patient's initial profile and isolated control points is challenging due to the high variability of recovery dynamics. Additionally, both the effect of chronicity on recovery potential and rehabilitation volume and intensity on recovery magnitude make accurate prognoses difficult.

On the other hand, the main medical success stories of modern AI have been in image analysis (segmentation, detection of anomalies), where they provide accurate and fast digital alternatives to the human pathologist. However, **at the level of clinical predictions, prognosis or therapy recommendations, despite massive investments, AI approaches have been unconvincing**. There one needs algorithms that, unlike deep learning AI, can be interpreted in terms of statistical models that allow for interrogation, can use domain knowledge, and can handle the imperfections and complications of real medical data (e.g., under sampling, confounders, informative censoring). The emerging consensus (which we support) is that the optimal approach to medical data analytics is a mixed strategy, based on integrating AI algorithms with interpretable Bayesian statistical models and mathematical techniques from theoretical physics to make the complex Bayesian computations feasible.

UNSATISFIED NEED OF POTENTIAL CUSTOMERS

STROKE PATIENTS as BENEFICIARIES:

1.LIMITED ACCESS TO AFFORDABLE TREATMENT: After a stroke, patients suffer a loss of motor and cognitive functions, which in many cases hinders their independence in ADLs. To recover, patients need several hours of therapy per day, but are lucky to receive 40 minutes of occupational therapy daily at public hospitals. Moreover, patients are discharged long before reaching their recovery potential due to the limited resources of staff and infrastructure at the hospital. After discharge, private rehabilitation is expensive (approximately 45€ for a 20-minute session) and many patients cannot afford the treatment volume they require and as a result their do not reach their full potential or their condition deteriorates.

2. POOR OUTCOMES: At the hospital, patients are not trained to take charge of their own recovery and are rarely supported during discharge. Instead, after discharge, patients normally have monthly control visits with their neurologist. Moreover, private treatment is expensive and unaffordable to many patients that still need many hours of rehabilitation. In some cases, patients suffer from so-called “learned non-use”, a vicious cycle of progressive low arm use and increased impairment. As a result, patients can lose up to 80% of the functional recovery achieved at the hospital after discharge, a phenomenon called "“Rehabilitation in vain” with obvious negative consequences on patients’ quality of life[16].

3. UNCERTAINTY ABOUT RECOVERY: Stroke patients often face significant uncertainty when it comes to their prognosis due to the varying opinions of health professionals, which can even be contradictory at times. This uncertainty can leave patients and their families feeling confused and anxious about their recovery potential. Due to this struggle to obtain a clear answer about their expected outcomes, patients may find themselves seeking multiple professional opinions to gain a more comprehensive understanding of their prognosis. This uncertainty is a heavy burden on patients and their families.

HEALTHCARE PROVIDERS as END USERS:

1. INCREASING COSTS: The rise in the elderly population is significantly contributing to an increase in the incidence and prevalence of neurological conditions. As individuals age, they become more susceptible to conditions such as Alzheimer's disease, Parkinson's disease, and stroke. The aging population often requires longer hospital stays, specialized treatments, and ongoing rehabilitation services, all of which contribute to rising healthcare costs. Given the projected demographic trends, this burden on hospitals and healthcare systems is expected to intensify in the coming decades, which calls for solutions that can “do more for less”.

2. STAFF SHORTAGE: In many healthcare settings, there is a shortage of clinical staff, which can hinder the provision of comprehensive and timely rehabilitation. The lack of resources, including healthcare professionals and specialized equipment, may limit the capacity to deliver optimal care to stroke patients. This scarcity leads to extended waiting periods and shorter therapy sessions. This is primarily attributed to the heavy workloads and high patient volumes, making it challenging to allocate adequate time to each patient and deliver the comprehensive care they need. The WHO estimates the shortage of trained health workers will go from 7.2

[16] Meyer, Sarah et al. “Functional and motor outcome 5 years after stroke is equivalent to outcome at 2 months: follow-up of the collaborative evaluation of rehabilitation in stroke across Europe.” *Stroke* vol. 46,6 (2015): 1613-9. doi:10.1161/STROKEAHA.115.009421

million in 2013 to 12.9 million by 2035. This crisis requires the creation of tools to increase the capacity of healthcare workers and hospitals.

3. READMISSION RATES: Stroke is a chronic condition that requires long-term management and preventive measures to reduce the risk of recurrent strokes. Healthcare providers face challenges in ensuring patient adherence to prescribed medications, lifestyle modifications (such as dietary changes and regular exercise), and follow-up appointments. Studies show that 6 months after discharge, 44% of stroke patients are readmitted due to a second stroke or other health deterioration-related issues. Maintaining patient commitment over the long term can be a struggle, and healthcare providers must find effective strategies to support patients in adhering to these crucial aspects of stroke management[17].

HEALTH INSURERS as PAYERS and BENEFICIARIES:

1. INCREASING PREVALENCE OF STROKE AND ASSOCIATED COSTS: The high and growing prevalence of stroke presents a significant challenge for health insurers. As the population ages and risk factors such as hypertension, obesity, and diabetes continue to rise, the number of stroke cases also increases. The burden of providing coverage for stroke rehabilitation services to many individuals adds to the financial strain on health insurers.

2. LONG-TERM CARE AND SUPPORT NEEDS: Stroke rehabilitation is not limited to the acute phase but often extends to long-term care and support. Many stroke survivors require ongoing therapy, medical monitoring, and assistance with daily activities. The long-term nature of stroke care can result in prolonged insurance coverage and increased costs for health insurers. For this reason, the better outcomes treatment can achieve and retain in the long-term, the more benefits for insurers.

3. HIGH COST OF READMISSIONS: The financial burden associated with readmissions places significant strain on health insurers, as they must cover the expenses of repeated hospital stays, rehabilitation services, and additional medical interventions. In the EU, readmissions cost in average 19.400€, with great variations depending on health complications. Implementing effective strategies to reduce readmission rates, such as enhanced post-discharge support, patient education programs, and continued care through telemedicine initiatives, can improve patient care and alleviate the financial pressure on health insurers.

3. THE INNOVATION: SOLUTION/PRODUCT OR SERVICES (USP)

OUR SOLUTION: THE RGS ECOSYSTEM

The RGS Ecosystem (RGS-E) integrates a set of intervention and monitoring solutions that are aligned with the patient journey to provide a continuum of care and leverage data from all phases of recovery to provide AI-based diagnosis and prognosis (Figure 2 and Free Annex).

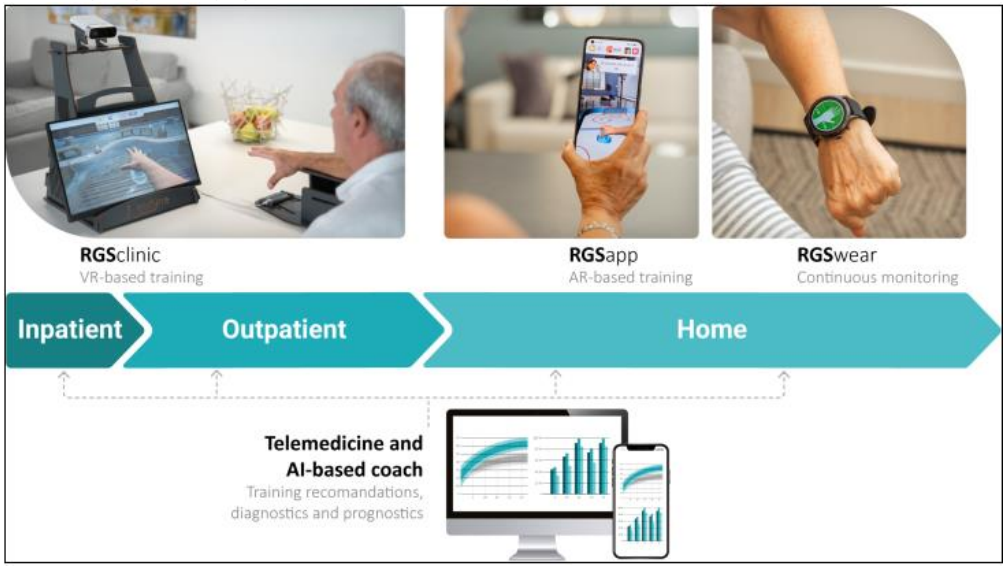

Figure 2: The RGS Ecosystem

INTERVENTION AND MONITORING

The end-user solutions that comprise RGS-E are: RGSclinic; a desktop workstation for VR training including a PC and a motion capture system to be used at the hospital during inpatient and outpatient treatment, RGSwear; a monitoring wearable device, and RGSapp; an Augmented Reality (AR) mobile app, for continuous

[17] Andersen, H E et al. "Can readmission after stroke be prevented? Results of a randomized clinical study: a postdischarge follow-up service for stroke survivors." *Stroke* vol. 31,5 (2000): 1038-45. doi:10.1161/01.str.31.5.1038

telerehabilitation delivery, remote monitoring, and feedback. The training protocols are delivered through immersive AR/VR scenarios with AI-based personalization. Additionally, the intervention applications include an AI-based coach to increase patient motivation and adherence to the neurorehabilitation programs. These affordable solutions leverage consumer electronics and provide intervention and monitoring at the clinic and at home. An MVP of RGSclinic is already commercialized for motor rehabilitation but needs to be further developed to target cognitive deficits, while TRL6 versions of RGSapp and RGSwear have been developed and need to be taken to TRL9.

DIAGNOSIS AND PROGNOSIS

We will leverage the data generated by RGSclinic (VR training at the hospital), RGSapp (AR training at home), and RGSwear (continuous monitoring of arm activity during ADLs) to create patient models based on Bayesian Inference Engines (see Free Annex). These models will assess and interpret the current state of the patient and provide clinicians with a prognosis of expected long-term recovery trajectory of the patient, combining treatment and potential adverse side effects relative to cohort data. This will allow us to **develop diagnostic and prognostic tools for clinical decision support**. Initial versions of these algorithms were designed and calibrated with legacy data, but they still need refinement and validations. The mathematical description of the patient models is presented in the Annex.

By following this approach, **we aim to transform consumer electronics, such as smartphones and smartwatches into tools for stroke recovery, diagnosis, and prognosis, targeting cognitive, motor, and speech rehabilitation**. By leveraging ubiquitous devices, we will provide scalable and affordable solutions aligned with patients' needs throughout the patient journey, filling gaps in care, supporting transitions and discharge, and leveraging valuable data to predict and optimize outcomes.

BREAKTHROUGH POTENTIAL

RGS-E is highly innovative because it will leverage AR/VR, computer vision, and Bayesian Inference Engines to transform end consumer electronics such as smartphones and smartwatches into tools for stroke intervention, diagnosis, and prognosis to ensure the care continuum. Patient behavior and recovery path will be modelled through mathematical expressions that will be transparent and interpretable, as opposed to deep learning models. Thus, the main innovative aspects of this project are:

(1) The objective **diagnosis and prognosis tools based on AI-patient modelling** respond to the complex dynamics of patient recovery, which is a significant departure from the current subjective assessments that are prone to human error. The use of advanced model-based adaptive statistical models that are transparent and can be interpreted and interrogated is also innovative and aligned with the emerging AI regulations in healthcare[18]. Currently, there are no comparable solutions in the market.
(2) We combine **science-based principles of neurorehabilitation with AR/VR technology** for intervention delivery, AI for treatment personalization, and massively distributed consumer electronics such as smartphones and smartwatches. Our aim is to provide home-based intervention solutions that are orders of magnitude more affordable than standard practice. This will enable patients to receive all the treatment they require instead of being limited by hospital capacity, as is currently the case.

Therefore, the **RGS ecosystem creates a new value chain that extends patients' clinical path from the hospital to their homes**. After a stroke, patients usually receive about ten days of inpatient rehabilitation followed by a treatment gap of 2 to 4 weeks, and finally approximately four months of outpatient rehabilitation. However, patients may lose up to 80% of their functional gains achieved in the hospital due to treatment discontinuation after discharge[19,20]. RGS-E can help avoid that patient health deterioration while providing remote monitoring and clinical decision support tools for professionals, thus avoiding unnecessary trips to the hospital and significantly prolonging treatment beyond discharge.

[18] https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai
[19] Löfgren, B et al. "Three years after in-patient stroke rehabilitation: A follow-up study." *Cerebrovascular diseases (Basel, Switzerland)* vol. 9,3 (1999): 163-70. doi:10.1159/000015948
[20] Meyer, Sarah et al. "Functional and motor outcome 5 years after stroke is equivalent to outcome at 2 months: follow-up of the collaborative evaluation of rehabilitation in stroke across Europe." *Stroke* vol. 46,6 (2015): 1613-9. doi:10.1161/STROKEAHA.115.009421

RGS ECOSYSTEM UNIQUE VALUE PROPOSITION

The RGS Ecosystem aims to transform consumer electronics into tools for comprehensive stroke intervention, diagnosis, and prognosis aligned with the patient journey. By leveraging widely used devices, RGS-E will enable global access to telerehabilitation, maximizing scalability and the volume of treatment offered by providers, thus **improving patient outcomes while reducing cost of care**.

1. **RGS-E SHORTENS OUTPATIENT TREATMENT BY 40%.** By speeding up patient recovery, RGS-E will accelerate discharge and shorten outpatient treatment length by 40%, drastically reducing the burden on hospital staff and ambulance trips (See Figure 3). Stroke management and care, including access to stroke units, varies greatly across Europe, and outpatient treatment can last from 0 to 12 months depending on the country. Moreover, due to limited resources (staff, infrastructure), stroke patients typically receive only 8 to 45 hours of rehabilitation per month at the hospital, with occupational therapists often handling multiple patients simultaneously at an hourly salary of around €12 (Spain). On the other hand, each patient costs the hospital approximately €18 per month for ambulance trips. Assuming an average treatment length of 5 months, by speeding up patient recovery and accelerating discharge by 40%, RGS-E could cut down 2 months, representing up to 90 hours of therapy at the hospital and 45 ambulance trips. Based on the information above, this could represent a cost reduction of €1.111,6 per patient, which translates to savings of €1.245 million and €884 million in the EU and US respectively, based on incidence numbers.
2. **RGS-E REDUCES STROKE READMISSIONS BY UP TO 41%** Furthermore, by using highly scalable and affordable devices that patients already possess and know how to use, RGS-E will reduce patient learning curves, fill the gaps between treatment phases, and ultimately facilitate the soft landing from the hospital to the patient's home, providing early-discharge support tools for rehabilitation and monitoring. Evidence shows that this approach could lead to a reduction in stroke readmissions of up to 41%[21] (See Figure 3). Approximately 44% of stroke patients discharged are at some point readmitted to the hospital due to a second stroke or other health deterioration-related issues, such as accidents (e.g., falls). Readmissions for stroke patients in Europe can average approximately €19.400, with great variations based on health complications. However, readmissions can be significantly reduced by implementing follow-up interventions. According to the Stroke Action Plan for Europe (SAP-E) 2018-2030, secondary prevention is suitable for almost all stroke patients and can reduce stroke recurrence by 80%, as well as other vascular diseases and complications such as cognitive decline and dementia, mood disturbances or anxiety, fatigue, and poor quality of life[22]. SAP-E also indicates that secondary prevention should continue throughout life. Based on existing literature, RGS-based interventions after hospital discharge could reduce readmission rates from 44% to 26%, effectively representing a cost reduction of €3.492 per stroke patient, translating to approximately €3,9 billion and €2,8 billion in the EU and US respectively, based on incidence numbers.

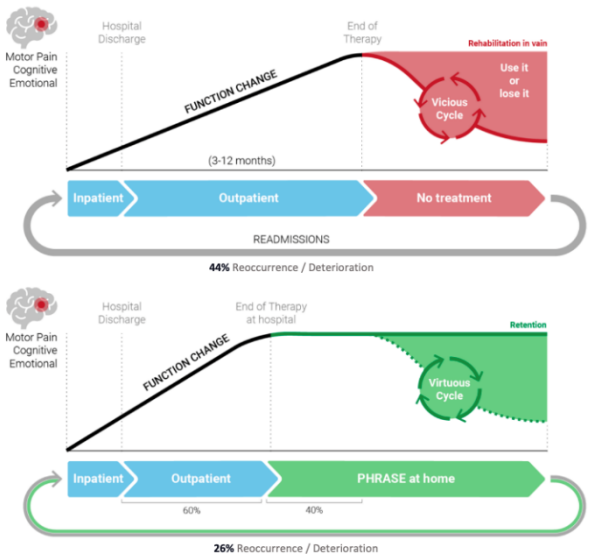

Figure 3. The current patient journey (top) and the impact of RGS-E on the patient journey (bottom).

3. **RGS-E DOUBLES THERAPY EFFICIENCY** Coupled with economic savings, there is an increase in the efficiency of resources that leads to greater treatment volume for patients, clinical efficiency for therapists, and capacity for hospitals. Thanks to telerehabilitation solutions that enable patients to train autonomously at home, RGS-E removes the obstacles that today are preventing patients from getting the treatment intensity they require (in some cases up to 5 or 6 hours daily), effectively tripling the volume of therapy delivered. At the same time, therapists will be able to manage more patients and reduce waiting times. Based on current

[21] Andersen, H E et al. "Can readmission after stroke be prevented? Results of a randomized clinical study: a postdischarge follow-up service for stroke survivors." *Stroke* vol. 31,5 (2000): 1038-45. doi:10.1161/01.str.31.5.1038

[22] https://actionplan.eso-stroke.org/domains/secondary-prevention

practices, one occupational therapist typically manages 12 patients per day. However, by providing clinical decision support tools for remote assessment, monitoring, and prescription, we estimate that therapists could manage each patient in 20 minutes, doubling their efficiency and capacity to 24 patients per day.

In conclusion, the RGS Ecosystem addresses the challenges in post-stroke neurorehabilitation by repurposing widely used consumer electronics for comprehensive intervention, diagnosis, and prognosis based on extensive scientific research. Through global access to telerehabilitation, RGS-E will enhance scalability and treatment volume, leading to improved patient outcomes and reduced costs. The system's ability to expedite patient recovery, shorten outpatient treatment lengths, and address disparities in stroke care across Europe will have a significant global impact, aligning with the SAP-E and Sustainable Development Goals. The integration of highly scalable devices into patient care not only bridges gaps in treatment phases but will also lead to significant reductions in waiting times and stroke readmissions. The resulting economic savings, coupled with increased resource efficiency, provide a transformative impact on stroke management, offering a cost-effective and scalable solution that benefits patients, therapists, and healthcare systems alike.

RGS ECOSYSTEM UNIQUE VALUE POINTS FOR OUR STAKEHOLDERS

The RGS-E approach is disruptive because it is the first solution to integrate state of the art intervention, diagnosis, and prognosis into a single, cohesive platform. Additionally, RGS-E sets itself apar by leveraging widely used consumer electronics that are highly affordable, enabling telerehabilitation and early supported discharge at scale. As a result, RGS-E offers the following advantages over competitors:

- **Alignment with patient journey:** RGS-E aligns strategically with the patient's journey, facilitating a smooth transition from hospital to home using familiar consumer electronics. It bridges treatment gaps, providing continuous support for rehabilitation and monitoring, minimizing readmission risks. Designed to accommodate the diverse stroke care landscape in the UE and US, it fosters a holistic, patient-centric approach to neurorehabilitation, enhancing overall care quality.
- **Greater Scalability:** One of the key advantages that RGS-E holds over competitors is its unparalleled scalability. Unlike hardware-based solutions that incur substantial costs related to equipment, shipping, installation, and maintenance, RGS-E's approach makes it financially viable to extend rehabilitation services to patients in the comfort of their homes.
- **Reduced Costs:** RGS-E offers significant cost savings by providing an affordable solution covering the entire rehabilitation pipeline – from admission and inpatient care to outpatient, discharge, and home-based treatment. This approach not only reduces the duration of hospital treatment but also facilitates early supported discharge, effectively lowering readmission rates.
- **Better outcomes:** RGS-E has demonstrated its ability to accelerate recovery and maintain long-lasting effects on arm use post-discharge, ensuring that patients not only regain but also retain functional gains to live fuller, happier, and more productive lives.
- **Comprehensive:** The RGS-E solutions address the full stroke symptomatology, covering motor, cognitive and language rehabilitation. This holistic approach makes it superior to competitors that focus on single domains, catering to the diverse needs of clinicians providing care to patients with varying requirements.
- **Higher accuracy:** The accuracy of prognosis models in RGS-E further sets it apart, boasting better resolution, longer time-scale predictions, and interpretability compared to current research efforts and potential competitors. The continuous update of clinical predictions with daily training data captures the intricate dynamics of recovery, diverging from reliance on single assessments.
- **Extensive evidence:** Finally, RGS-E stands on a solid foundation of clinical evidence, with its scientific approach being rigorously validated in over 45 research papers spanning the past two decades. The empirical evidence substantiates that RGS-E consistently delivers superior outcomes for patients when compared to standard therapy, establishing its credibility and efficacy in the neurorehabilitation landscape.

DEVELOPMENT STAGE (TRL)

RGS Ecosystem is currently at TRL 6. Figure 4 illustrates the Evolution of Technology Readiness Levels (TRL) for Eodyne's technology by showcasing the progression and maturation of our technology over time:

TRL 1-3: INITIAL STUDIES ON VR APPROACH FOR MOTOR RE-LEARNING (2005-2014).

Eodyne emerged as a direct outcome of the successful clinical validation of the Rehabilitation Gaming System (RGS) research project. The project, funded by the Active and Assisted Living (AAL) Program in 2009, focused on a novel VR approach, based on Prof. Paul Verschure's DAC theory of mind, to address stroke motor rehabilitation.

SPECS lab carried out the project in collaboration with hospitals Vall de Hebron Hospital (Barcelona, Spain), La Esperanza (Barcelona, Spain) and Sant Joan de Deu (Tarragona, Spain). The initial studies laid the foundation of the scientific principles behind the motor re-learning VR-based protocols in RGSclinic. **Eodyne was established in 2014 to translate the project results into a marketable product for patients and clinicians.**

TRL 4-5: CLINICAL BENEFITS OF RGS STUDIED IN ACUTE, SUB-ACUTE, AND CHRONIC PATIENTS, BOTH IN CLINIC AND DOMICILIARY CONTEXT (2015-2020).

After the initial development and validation of the scientific approach, the research was extended to cover other stroke related impediments beyond the motor function, to include cognitive, language, and affective impediments. This was a critical aspect not only for clinical purposes, but also commercially since most stroke patients present deficits across all these functional domains. Therefore, many more clinical studies were conducted to assess the efficacy of the approach in the different symptomatology domains. To the date, over 45 scientific papers have been published showing the clinical effects of the RGS approach, the main results are summarized below:

- **2015: The clinical benefits of the system have been studied in acute, sub-acute and chronic patients, both at the clinic and in the domiciliary context**[23]. In comparison to occupational therapy, the RGS showed a positive impact in paretic arm speed, and functional and structural recovery as captured by standardized clinical scales (Figures 4 and 5). Improvement was observed not only in range of motion, speed, and strength, but also in the performance of activities of daily living and independence[24,25,26]. Specifically, patients treated with the RGS presented a significantly faster improvement during the acute and subacute phase compared to standard treatment already at month three, even with low-intensity training (20 minutes/3 times a week) and reached a higher level of recovery at the chronic stage. Similarly, we have shown that, so-called, acquired non-use in stroke patients can be restored in a single session when perceived actions are amplified in virtual reality in an intention compatible fashion[27] where no other alternative exists, i.e., the dominant treatment of Constraint Induced Movement Therapy (CIMT) has been shown to not work consistently. These changes in upper limb

Figure 4: TRL evolution of the technology

[23] Ballester, B. R., Nirme, J., Camacho, I., Duarte, E., Rodríguez, S., Cuxart, A., ... & Verschure, P. F. (2017). Domiciliary VR-Based Therapy for Functional Recovery and Cortical

[24] Cameirão, M. S., Bermúdez i Badia, S., Duarte, E., & Verschure, P. F. (2011). Virtual reality based rehabilitation speeds up functional recovery of the upper extremities after stroke: a randomized controlled pilot study in the acute phase of stroke using the rehabilitation gaming system. Restorative neurology and neuroscience, 29(5), 287-298.

[25] Cameirao, M. S., i Badia, S. B., Duarte, E., Frisoli, A., & Verschure, P. F. (2012). The combined impact of virtual reality neurorehabilitation and its interfaces on upper extremity functional recovery in patients with chronic stroke. Stroke, 43(10), 2720-2728.

[26] Duff A., Duarte E., Cuxart A., Rodriguez S., Cameirão S., Bermúdez S., Verschure P., Rehabilitation Gaming System (RGS): The Impact Of Virtual Reality Based Training On Upper Limb Recovery In The Acute And Chronic Phase Of Stroke, Cerebrovascular Diseases 31 (2011).

[27] Ballester et al., "The Visual Amplification of Goal-Oriented Movements Counteracts Acquired Non-Use in Hemiparetic Stroke Patients."

spontaneous use were associated to sustained functional gains[28], reaching a mean improvement of 13.89 ± 9.88 SD points in the UE-FM scale.

- **2018**: **The benefits of RGS on spasticity, pain and depression have been also suggested in post-hoc analyses of recovery in chronic hemiparetic patients**[29] Further, a meta-analysis revealed that increasing the RGS therapy dosage did not influence recovery in acute patients, but it did show a significant effect at the sub-acute and chronic stage[30]. Altogether, these results support the existence of biological processes of recovery that are unique to the injured brain at the acute phase. These mechanisms may be masking the specific benefits of sustained practice at early stages post-stroke. In contrast, at the chronic stage, improvements captured by the Fugl-Meyer scale may be mostly driven by general principles of motor learning, which are modulated by therapy dose. The impact of RGS in the context of a multiplayer rehabilitation scenario has also been investigated. Patients performing in multiplayer mode were found to perform wider extension movements of the upper limbs[31] and improved self-efficacy and satisfaction in comparison to single-player mode[32],[33].
  In addition, **we have uniquely shown that by delivering an integrated action and language aphasia rehabilitation protocol RGS can deliver better long-term outcomes than intense language therapy**[34] We show that these patients not only show improvement after treatment but as well continue to improve in vocabulary-related changes (mean 15.68 ± 7.4 SD, P=0.01), language (mean 10.22 ± 8.19 SD, P=0.01) and communication (mean 9.62 ± 11.30 SD ,P=0.05) 2 months after the treatment ended.
- **2020**: Lastly, **RGS has been successfully applied to cognitive and affective rehabilitation**[35] realizing the only system in research and the market that addresses all domains affected by stroke. Our research demonstrated that RGS adapted optimally to the different cognitive impairment levels of the patients which consequently showed improvements in attention (mean 0.41 ± 0.46 SD, χ^2_F (2) = 9.57, p < .01), spatial awareness (mean 3.21 ± 6.57 SD, χ^2_F (2) = 11.23, p <.01) and generalized cognitive functioning (0.44 ± 0.42 SD, χ^2_F (2) = 15.5, p < .001). Together with the scientific and technological developments, **Eodyne received a License as a Manufacturer of Medical Devices by the Spanish Agency for Medicines and Medical Devices (AEMPS) and in 2016, certified RGS with the CE mark as Medical Device Class 1.**

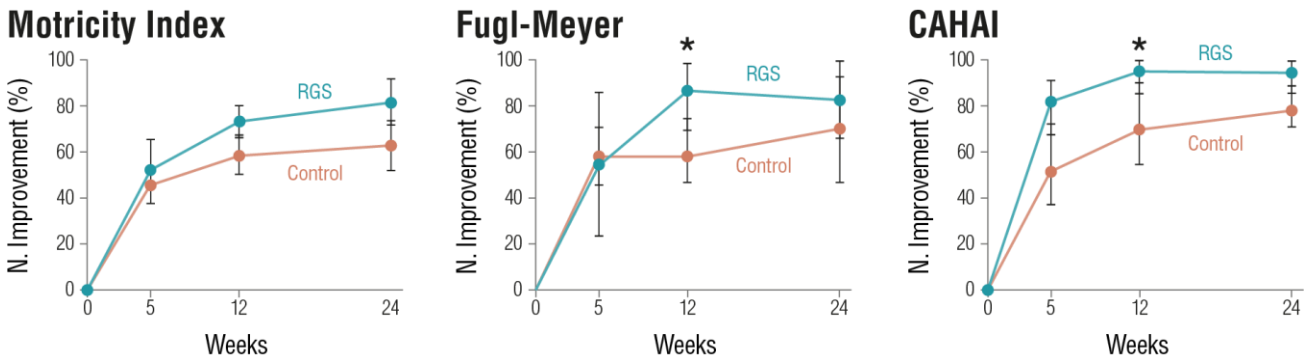

Figure 5: Normalized improvement over time for the Motricity Index, the arm subpart of the Fugl-Meyer Assessment Test and the Chedoke Arm and Hand Activity Inventory, at mid intervention (w5), end of intervention (w12) and follow up (w24), *p < 0.05.

[28] Ballester, B. R., Maier, M., Mozo, R. M. S. S., Castañeda, V., Duff, A., & Verschure, P. F. (2016). Counteracting learned non-use in chronic stroke patients with reinforcement-induced movement therapy. Journal of neuroengineering and rehabilitation, 13(1), 74.
[29] S. Rodriguez, S. B. i Badia, M. D. Cameirão, A. C. Fina, E. Duarte, A. Du↵, P. Verschure, Session 225 Effects of Virtual Reality Upper Limb Based Training (Rehabilitation Gaming System) on Spasticity, Shoulder Pain, and Depression After Stroke, PM&R 3
[30] Ballester, B. R., Grechuta, K., Maier, M., & Verschure, P. (2018). Extending the Proportional Recovery Rule to Virtual Reality Based Neurorehabilitation. European Stroke Conference 2018
[31] Ballester, B. R., i Badia, S. B., & Verschure, P. F. (2012). Including social interaction in stroke VR-based motor rehabilitation enhances performance: a pilot study. Presence, 21(4), 490-501
[32] Maier, M., Ballester, B. R., Duarte, E., Duff, A., & Verschure, P. F. (2014, April). Social integration of stroke patients through the multiplayer rehabilitation gaming system. In International Conference on Serious Games (pp. 100-114). Springer, Cham.
[33] Marwecki S, Ballester BR, Duarte E, Verschure PFMJ. Goal-oriented feedback on motor behavior in virtual reality based stroke therapy: A case study using the rehabilitation gaming system. Edorium J Disabil Rehabil 2017;3:36–45.
[34] Grechuta et al., "Augmented Sensorimotor Dyadic Therapy Boosts Recovery in Patients with Nonfluent Aphasia: A Randomised Controlled Trial."
[35] Maier et al., "Adaptive Conjunctive Cognitive Training (ACCT) in Virtual Reality for Chronic Stroke Patients: A Randomized Controlled Pilot Trial."

TRL 6: VALUABLE FEEDBACK FROM CLINICAL STUDIES AND CUSTOMER ENGAGEMENT USED TO IMPROVE TECHNOLOGY'S ROBUSTNESS AND USABILITY (2017-2024).

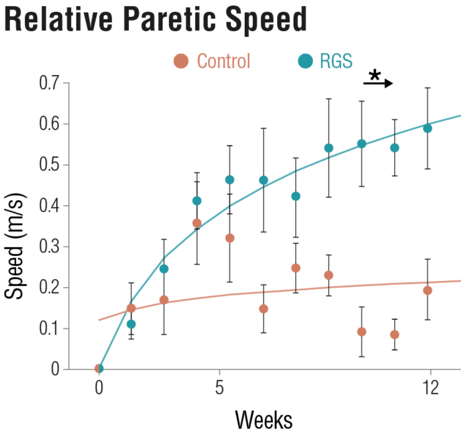

Figure 6: Relative average speed (mean ± standard error of the mean) over time for RGS and control groups. The time series are fitted with log curves), *p < 0.05.

- Since 2017, we have **focused on enhancing user-friendliness and accessibility of the solution by developing interfaces and an online dashboard for healthcare professionals**. We have also created additional training activities with improved gamification and have worked on enhancing the overall user experience (UX). Currently, **RGSclinic is being utilized in approximately 20 hospitals and clinics to treat motor impairments.**

  Through engaging with these stakeholders, we have identified two major concerns expressed by our customers. Firstly, professionals such as neurologists and occupational therapists **struggle to accurately assess and communicate to patients how much function they can expect to regain**. This uncertainty often places an emotional burden on patients and their families, causing anxiety about their potential for recovery. Secondly, after discharge, patients often cease to receive treatment and experience significant functional deterioration. **Studies have shown that stroke patients can lose up to 80% of the functional gains achieved in the hospital** due to the discontinuation of treatment. This phenomenon, called "rehabilitation in vain" to describe the waist of hospital resources not only impairs the patient's quality of life but also contributes to high readmission rates.

  To address these issues, in **2019 we set out to develop solutions for home-based training and in the RSG@home project, funded by EIT Health**. During this project, we created and validated a compact version of RGSclinic to train at home. This version prioritizes simplicity, user experience, and autonomy, enabling stroke patients to interact with the system without the need for supervision or assistance. Improvements brought by this version include the removal of arm sensors, the development of training routines, a significant reduction in space requirements, and click-and-play features for easier access. This solution was clinically validated in collaboration with hospitals Sant Joan de Deu (Spain), University Hospital of Limoges (France), and Uppsala University Hospital (Sweden) with over 65 patients at home. The results showed significant improvements in grip strength and pain reduction, as well as elevated adherence levels. Also, during the RGS@home project, initial versions of the diagnosis and prognosis algorithms were developed in collaboration with SaddlePoint Science. The first versions of these models were based on an adaptation of the Gaussian Process Latent Variable Model (GPLVM). All parameters in the GPLVM model, their associated hyper-parameters, and the dimensionality and definition of the latent variables are inferred using Bayesian protocols. The rationale is that optimal individualized activity selection will be detectable in the observed patient performance, giving further valuable information that can be used in inference and decision support. These initial models were calibrated and trained with RGS legacy data (owned by Eodyne) and with patient data coming from the RGS@home project, collected from over 65 patients training at home for 3 months.

  The later stages of the RGS@home project were disrupted by COVID-19, which gave us a real-world opportunity to test our solution. We found that hardware costs (PC, infrared camera, plus accessories) although optimized, were still too high for deployment at scale for most hospitals, especially during the pandemic outbreak where hospital resources where under extreme pressure. For this reason, we developed RGSapp, a smartphone app that uses AR to provide motor and cognitive training deployable via app stores. This was achieved towards the end of the RGS@home project and therefore its validation only reached usability testing levels.

- **The technology has been taken to TRL 6 under the PHRASE project, led by Eodyne and funded by the EIC Transition Programme**. PHRASE is building a pipeline for continuous intervention, monitoring and data processing aligned with the patient's journey, offering a seamless transition from hospital to home. At the hospital, during inpatient and outpatient phases of treatment, recovery is accelerated by RGSclinic as shown by the clinical evidence[36]. After discharge, rehabilitation and monitoring is provided via RGSapp and RGSwear, smartphone and smartwatch apps, respectively, that reduce the learning curve for users by utilizing familiar consumer electronics to ensure a soft landing from the hospital to patient's home. This approach ensures that patients receive continuous support emphasizing early supported discharge and minimizing the risk of

[36] https://www.eodyne.com/rgs-is-clinically-validated-publications/

readmissions. Also in the PHRASE project, the algorithms for diagnosis and prognosis are being further developed and trained to leverage the data collected throughout the different treatment phases through the solutions above mentioned to capture the complex recovery dynamics in stroke and provide higher predictive resolution and accuracy. The flexibility of the architecture proposed caters to the diverse stroke care landscape across Europe, addressing disparities in stroke management and care, and enables to fill the gaps between treatment phases (eg, between inpatient and outpatient phases), where currently patients are provided no treatment. This alignment with the patient's journey enables a comprehensive and patient-centric approach to neurorehabilitation, ultimately enhancing the general standard of care. The PHRASE technology is currently undergoing clinical trials with stroke patients at the Institute for Functional Rehabilitation La Salle (Madrid, Spain), Hospital Vall de Hebrón (Barcelona, Spain), Sint Maartenskliniek (Nijmegen, The Netherlands), INRCA (Ancona, Italy), University Hospital of Limoges (Limoges, France), and Cluj Rehabilitation hospital and Cluj County Emergency Hospital (Cluj, Romania).

TRL 7-8: EIC ACCELERATOR RGS ECOSYSTEM PROJECT (2025-2027). Here, **we will take the neurorehabilitation solutions for monitoring, intervention, and prognosis to TRL 8 to get them ready for market launch. The main steps to get the solutions to TRL 8 are:**

TECHNOLOGICAL DEVELOPMENT (WP1 and WP3)

- **RGSapp:** To enhance the functionality and treatment scope of RGSapp, we plan to collaborate with suppliers to integrate the app with external devices. This integration will help address adaptation and ergonomic issues, such as the use of anti-gravity devices, and expand the range of treatments. For example, we aim to incorporate grip pressure sensors and haptic feedback into RGSapp, enabling users to receive real-time feedback and engage in more diverse motor and cognitive training exercises. This integration will provide a more comprehensive and tailored rehabilitation experience for patients.
- **RGSclinic:** Our focus for RGSclinic is to develop a monocular 3D body tracking algorithm. By implementing this algorithm, we aim to reduce the equipment requirements (i.e. dedicated sensors such as infrared cameras) of the current RGSclinic solution. This reduction in equipment will not only lower costs but also increase the scalability and usability of RGSclinic. Hospitals and patients will be able to benefit from the system with a simplified setup, making it more accessible in various clinical settings.
- **RGSwear:** To make RGSwear more affordable and accessible, we are planning to develop a custom-made bracelet. This custom-made bracelet will serve as a wearable solution to monitor and foster arm use, similar to the existing RGSwear. By designing a dedicated bracelet, we aim to reduce equipment costs for users while maintaining the effectiveness of the monitoring and training capabilities. This cost reduction will enhance the affordability and usability of RGSwear, ensuring that a wider population can benefit from its features.
- **LLMM models:** As part of our ongoing research and refinement efforts, we will focus on enhancing the accuracy and reliability of the LLMMs. We will investigate patient extrinsic factors that may influence the recovery path of patients, such as family environment, socio-economic status, and other co-occurring conditions. By considering these non-pathology related factors, we aim to enhance the predictive capabilities of the LLMM models and provide more comprehensive insights into the recovery journey of stroke patients. This research will contribute to refining the models and improving their applicability in clinical settings, supporting personalized and targeted rehabilitation strategies.

VALIDATION AND REFINEMENT (WP 2, 4 and 5)

- **Feasibility Study**: A feasibility study with stroke patients will be conducted to gather user feedback and assess the effectiveness of RGSclinic, RGSapp, and RGSwear in providing motor and cognitive training and monitoring through AR/VR in clinical and home contexts. The study will focus on usability, effectiveness, user satisfaction, and any limitations or issues identified during the evaluation.
- **Refinement and Optimization:** Based on the results and feedback from the feasibility study, the RGS solutions will undergo refinement and optimization. The identified issues or limitations will be addressed to improve the user experience, functionality, and overall effectiveness solutions so these are mature enough for a clinical trial.
- **Clinical Trial**: A clinical trial will be conducted involving stroke patients to evaluate the clinical impact of the intervention solutions in their final form on motor and cognitive function. Collaborations with clinical partners across Europe will ensure a diverse patient population, enabling a comprehensive assessment of the solutions' efficacy. The trial will measure the outcomes and benefits of using the solutions in terms of motor and cognitive improvements, patient engagement, and overall rehabilitation progress.

- **Data Collection for LLMM Models:** To ensure the predictive capabilities of the LLMMs in assessing the pathway to recovery for stroke patients, all necessary data will be collected. This will involve capturing patient information, including clinical assessments and measurements of arm functionality, as well as relevant patient extrinsic factors (such as family environment, socio-economic status, and co-occurring conditions).
- **Data Analysis:** The collected data from the clinical trials will be analyzed to assess the clinical relevance and predictive accuracy of the LLMM models. Statistical analyses and machine learning techniques will be applied to examine the relationships between patient characteristics, intervention outcomes, and the predicted recovery pathway. The analysis will provide insights into the effectiveness of the LLMM models and their potential to inform personalized rehabilitation strategies.
- **Refinement and Optimization:** Based on the findings and insights from the clinical trials, the RGS solutions and LLMM models will undergo further refinement and optimization. The feedback, data analysis, and evaluation outcomes will inform iterative improvements to enhance the functionality, accuracy, and clinical impact of the solutions.
- **Documentation:** Comprehensive documentation, including user manuals and guidelines, will be prepared to support the implementation of the developed solutions in both clinical and home settings. The documentation will also include best practices and recommendations for incorporating the LLMM models into clinical decision-making processes. This documentation will be an input for the MDR and FDA certification processes.

IP STRATEGY

Eodyne Systems has a global, exclusive license for the RGSclinic technology from Universitat Pompeu Fabra in 2014. Under this agreement, Eodyne must pay 5% royalties for one component of the Ecosystem, RGSclinic, until 2025. After this year, no further royalties are required. The rest of the intervention and monitoring solutions were developed independently and are Eodyne's property. The diagnosis and prognosis algorithms are being developed in collaboration with SaddlePoint Science, with whom Eodyne has signed a worldwide exclusive commercialization and revenue sharing agreement stating that Eodyne is the only company with exploitation rights globally, for which a 7% of the profits are destined to SaddlePoint. Moreover, Saddlepoint's diagnosis and prognosis algorithms where designed and trained specifically with RGS data and are not usable independently from RGS-E.

Eodyne has outsourced a **FREEDOM TO OPERATE (FTO) ANALYSIS** to the company ZBM Patents & Trademarks. The conclusions of the FTO (the full report is included in the annex) are:
- The risk of infringement of the patents and patent applications considered most relevant in the FTO report, in a member state of the European Patent Convention by the methods and systems developed by Eodyne, is low.
- The scope of protection of the patent documents retrieved in the searches appears to be limited to features that are not reproduced by Eodyne.
- Thus, the method and system implemented by Eodyne do not reproduce the combination of all the features of the independent claims that define the scope of protection of the patent documents retrieved.

Eodyne will continue to work with ZBM Patents & Trademarks to analyze possible Patents, Copyrights, and Trademarks. Among the potentially patentable results, we consider:

- AI models and their corresponding software developments for clinical decision support and rehabilitation intervention design.
- Adaptations of present EODYNE's RGS neurorehabilitation solutions (in principle, RGSclinic, RGSapp, and RGSwear) for their use with the AI modules for clinical decision support and intervention design.
- Other intermediate results that may be patentable include a 3D monocular tracking system
- A stroke AR-based diagnosis application.

4. MARKET ANALYSIS AND COMPETITION ANALYSIS

MARKET OVERVIEW

TOTAL ADDRESSABLE MARKET (TAM)

The science behind RGS-E has been extensively tested and validated on stroke patients. However, the scientific principles for neurorehabilitation and brain plasticity are transversal and can be applied to many other high-incidence neuro-pathologies, including Traumatic Brain Injury (55M), Chronic Pain (60M), Alzheimer´s disease (50M), Cerebral Palsy (17M), Multiple Sclerosis (2.8M), Parkinson´s disease (13M) and Spinal Cord Injury (27M). Combined with stroke, the prevalence of these neuropathologies add up to more that 306 million patients living in the word. On top of that, musculoskeletal disorders, with more than 1.710 million patients globally, are the leading cause of disability and the main factor contributing to the need for rehabilitation worldwide.

Musculoskeletal disorders range from sudden and short-term conditions, such as fractures, sprains, and strains, to chronic diseases that cause limitations in functional abilities, which are potentially treatable with the RGS-E technology. Therefore, the total number of potential users is the world is over 2.016 million patients. Assuming a monthly revenue per patient of 24€, as we will explain in the financial projections section, this translates into a TAM of approximately 581€ billion.

SERVICEABLE AVAILABLE MARKET (SAM)

We will begin by focusing on stroke, as most of the scientific evidence has been generated with stroke patients. There are over 13.5 million stroke cases every year and 81 million chronic stroke patients living in the world. Of these roughly:

-10% of patients recover almost completely.
-25% of patients recover with only minor impairments.
-40% of patients experience moderate-to-severe impairments that require special care.
-10% percent of patients require long-term care.
-15% of patients die shortly after

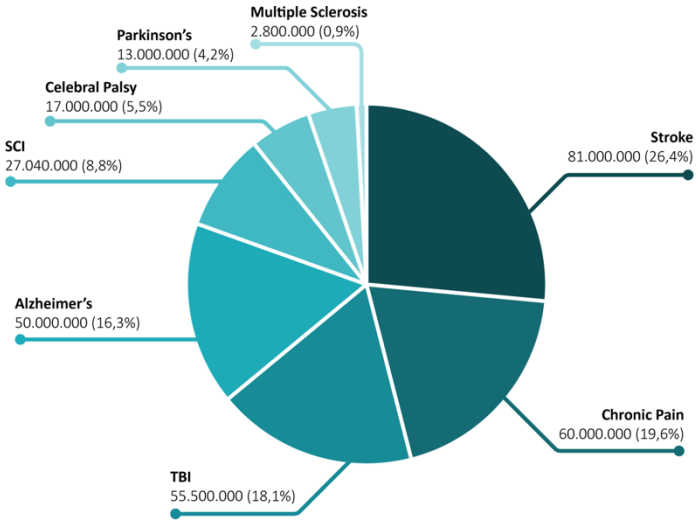

Figure 7. Worldwide prevalence of neuropathologies that could benefit from RGS-E.

Assuming our serviceable market as the 40% of patients with moderate-to-severe impairments that would benefit from rehabilitation, and that we focus on the markets within Europe, US, and Latam, which present a stroke prevalence of 9.5, 4.7, and 5.5 million respectively[37], we estimate the total number of addressable patients at approximately 8 million. Again, considering a 24€ monthly revenue per patient, these prevalence numbers translate to a 2,3€ billion SAM.

SERVICEABLE OBTAINABLE MARKET (SOM)

We have estimated our sales projections with a bottom-up model, establishing sales teams in our target markets to develop distribution channels and manage distributors. Over the first 6 years of commercialization, we have projected sales in the main European markets, the US, and Mexico and Brazil. In these years, the business development and marketing staff will grow from 17 to 45 people, and we expect to reach 1.635 hospitals and 186.206 patients and to generate approximately 52M€ in yearly revenue. This represents approximately 5% of all patients in need of rehabilitation in our target markets.

COMPOUNDED ANNUAL GROWTH RATE (CAGR)

The Global Neurorehabilitation Devices Market size was valued at 2.2€ Billion in 2022 and is projected to grow from 2.6€ Billion in 2023 to 8.5€ Billion by 2031, at a CAGR of 15.9% during the forecast period (2024-2031)[38]

WILLINGNESS TO PAY

We offer our key stakeholders quantifiable and demonstrated benefits, which will have a clear impact on their willingness to pay:

- **We have early adopters of RGSclinic's (our VR solution for motor recovery) MVP version as a stand-alone product**. Among these early customers we highlight Hospital Vall de Hebron (Barcelona, Spain), Centro Cerebro (Braga, Portugal), and Sint Maartenskliniek (Nijmegen, The Netherlands). These rehabilitation centres pay approximately 3.000€ per year for the RGSclinic license. Additionally, Eodyne is a homologated provider to Roche Diagnostics, who is paying Eodyne €35 per patient treated per month at Bellvitge Hospital (Barcelona, Spain).
- **We have outsourced a preliminary market study** (please refer to Free Annex), contacting neurologists and general practitioners from five European countries, who expressed that would be willing to pay 100€ per patient/month for a telerehabilitation solutions like RGSapp. We have summarized the results of this market study in the annex.

[37] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9904132/
[38] https://www.giiresearch.com/report/sky1441199-global-neurorehabilitation-devices-market-size.html

- Readmissions is one of primary drivers of stroke costs, with readmission length of stay being approximately three times that of the initial hospitalization[39]. This is a **great incentive for payers to reduce avoidable readmissions as much as possible.** An example of this is Medicare's Hospital Readmissions Reduction Program (HRRP)[40], in which hospitals are penalized for excessive readmissions for certain diseases. A key aspect to reduce readmissions is to foster self-management and prevent patient health deterioration by providing early support discharge and continuity of care.

COMPETITOR ANALYSIS

The neurorehabilitation devices market is rather fragmented with no clear leader and several new companies coming into the market every year to compete for market share. **Algorithm-based prognosis used in the clinical context** today require clinical predictors and corticospinal tract biomarkers assessed within 72 hours from the stroke and they predict in a scale of 1 to 4 functional outcome categories at 3 months poststroke. As such, these solutions are low resolution and short term. Also, these algorithms require both human experts to diagnose the patient and transcranial magnetic stimulation which is not easily available. Importantly, the current efforts towards transparent and interpretable **stroke prognosis algorithms are still in the research stages**. We highlight the Shirley Ryan Ability lab (USA), Yong-jun Wang and Yong Jiang groups in Chinese Academy of Medical Sciences (China), Giovanni D'Addio and Domenico Scrutinio research group in Istituti Clinici Scientifici Maugeri IRCCS (Italy), Margit Alt Murphy research group at University of Gothenburg (Sweden), Antonio Cerasa group in IRIB CNR (Italy), and Gert Kwakkel group at VU University Medical Centre (Netherlands). The main characteristics of these groups and research initiatives have been summarized in a table in the Free Annex. Therefore, in this domain, the biggest threats are possible spin-off companies created to commercialize potential future results of the ongoing research. However, these solutions either have low resolution, don't predict long-term, involve deep learning techniques that are not explainable or interpretable by humans, or require data that might be expensive or unavailable, such as MRI.

Our prognosis model is interpretable and explainable, and is integrated within the neurorehabilitation intervention, thus, its constantly getting data from daily training and adjusting predictions accordingly (as opposed to relying on a few isolated clinical assessments). **This novel approach is what allows us to predict further into the future and with higher resolution (1 to 100 scale).**

Regarding **neuro-rehabilitation solutions**, there are several companies offering a diverse range of products, as mentioned above. For our analysis (see Figure 8), we have identified those companies that present similarities with the different components of the RGS Ecosystem. These are our **DIRECT COMPETITORS**, although we have not found current competitors that cover the entire patient journey including both hospital and home-based treatment.

- MINDMAZE **(Switzerland)** shares partial similarities with our solution. While both companies target hospitals and clinics, Mindmaze exclusively offers intervention solutions for inpatient and outpatient treatment, lacking the comprehensive monitoring, diagnosis, and prognosis telemedicine tools provided by our platform. Notably, their reliance on dedicated hardware, such as an infrared camera for body tracking, contributes to a higher cost compared to our approach, which utilizes widely available consumer electronics like smartphones and smartwatches. Mindmaze's solution is well-suited for hospital settings but lacks scalability for home-based treatment. Furthermore, our solution, RGS, boasts a more extensive clinical evidence base. In contrast, Mindmaze has implemented collaborative projects in European hospitals but shows limited evidence of customers actually paying for their product. Despite significant capital raised, Mindmaze appears to be diversifying its focus beyond rehabilitation, delving into applications in other domains such as automotive technology.
- EVOLVREHAB **(Spain)** is a competitor comparable to Mindmaze. Their solution depends on dedicated hardware for motion tracking, therefore, while appropriate for hospital use, EvolvRehab lacks the scalability to compete in the home-based rehabilitation market. To this date, EvolvRehab has delivered 8500 gaming sessions and 900 hours of gaming among the different types of patients who are using it, mainly with neurological and cerebrovascular diseases (acquired brain injury, Parkinson's, Alzheimer's, dystrophies and multiple sclerosis). However, their solution was originally designed to address multiple sclerosis and as a result, their fundamental product concept fails to address the needs of a very relevant portion of the stroke population, which is patients

[39] Johnson B, Bonafede M, Watson C. Short- and longer-term health-care resource utilization and costs associated with acute ischemic stroke. *Clinicoecon Outcomes Res*. 2016;8:53-61 https://doi.org/10.2147/CEOR.S95662

[40] https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/hospital-readmissions-reduction-program-hrrp

with mild to severe hemiparesis. These patients are unable to raise the arms on the air, only being able to carry out "non-gravity" exercises over a table top, which EvolvRehab does not offer. Eodyne distinguishes itself from EvolvRehab by offer more scalable and comprehensive solutions for stroke rehabilitation, backed by significantly more scientific evidence, and by providing diagnosis and prognosis tools coupled the intervention programs, which EvolvRehab lacks altogether.

- JINTRONIX (Canada) offers intervention-only solutions that rely on dedicated hardware (Infrared camera, gaming PC) for body tracking. Their main customers are hospitals and clinics, and they offer as solution that is not adapted to the home environment due to equipment costs and space requirements, so they are limited to inpatient and outpatient treatment. Jintronix has published 8 peer-reviewed papers and is present in the US and Canada, but not in Europe. Jintronix also lacks the clinical decision support tools for diagnosis or prognosis offered by Eodyne.
- REHAMETRICS (Spain), as many competitors in this space, Rehametrics requires dedicate hardware, such as infrared cameras and VR Head-Mounted Displays (HMD), to run their motor rehabilitation solutions. Rehametrics distinguishes itself by offering detailed reports on patient motor function, such as precise joint range of motion measurements and core control metrics. They have 20 publications in scientific journals and conferences. They are present in 10 countries and used by more than 200 healthcare organizations. However, Rehametrics does not offer prognosis tools and is not adequate as a telerehabilitation product due to its equipment costs and their need for therapist presence to personalize the therapy, and therefore will not be able to compete with Eodyne on the home-based rehabilitation market.
- SAEBO (USA) holds a large market share in stroke rehabilitation since 2004. Headquartered in North Carolina, it has distributors worldwide and a European subsidiary in the UK. Saebo signed an agreement with Barron Associates for an exclusive marketing and distribution of their Virtual Occupational Therapy Application (VOTA) technology, which is sold under the name SaeboVR. It presents technological features equivalent to RGSclinic, based on a Microsoft Kinect sensor connected to a personal computer to perform simulated activities of daily living (ADLs). However, its price is significantly higher when compared with RGS, amounting to $12,000. Its use in the USA is approved in both clinical and home setting but only under supervision of a medical professional, which is not always possible in a home environment. Treatment with SaeboVR is covered by the Medicare public health program, which facilitates its commercialization in the US.

INDIRECT COMPETITORS. Our indirect competitors do not use AR/VR to deliver neurorehabilitation, but their products fulfil similar functions or cater to our customer base and could draw potential customers away. We have paid special attention to competitors that have successfully deployed at scale, such as Sword Health and Lumosity, and thus constitute potential threats.

- SWORD HEALTH (Portugal) provides portable solutions for rehabilitating and diagnostics and prognosis. They are an indirect or potential competitor, as they treat exclusively musculoskeletal disorders, which do not involve neurological lesions. This approach is effective for injury trauma, but not for stroke or other neuropathologies. Sword Health claims to have reached over 220 million patients and 800.000 healthcare providers, which demonstrates their product is scalable. However, they do require a small equipment set that includes inertial body sensors and a tablet, which would give Eodyne's software-only solutions a cost advantage in case they moved into the neurological market.
- LUMOSITY (USA) distinguishes itself from the previous competitors in that they are a software-only product. They offer a smartphone application sold over app stores and is therefore more scalable. Lumosity addresses brain training for the general audience and patients with cognitive impairments, which includes the stroke market, and offers a variety of well-designed exercises. They have reached 100 million members, but most likely these are mostly healthy individuals looking to improve cognitive skills and not patients. Nevertheless, Lumosity's main limitation is that they only treat cognitive impairments and do not offer any solution for motor rehabilitation (eg, upper limb, hand, core control, balance). Most stroke patients that seek rehabilitation need some sort of physical therapy, so Lumosity is unlikely to cover their needs.
- KINESTICA (Slovenia) develops Bimeo, an arm rehabilitation system that allows unilateral and bilateral exercises in unimanual or bimanual mode. Its system consists of 5 products mounted on a support surface to offer gamified therapy with more than 20 scenarios to train cognitive tasks and activities of daily living, but also fun games. Although it is indicated for patients suffering from neurological disorders or musculoskeletal impairments, it is not considered a direct competitor, as the motion detection technology is not through cameras but through sensors placed on the arm and it requires an additional support and products.
- BIONIK (USA) has an extensive evidence base of more than 25 years on its robotic products to assist in upper limb rehabilitation for patients with neurological conditions. Additionally, they have an evaluation system to track

the patient's progress and create customised reports to provide the most appropriate treatment. The main drawback of InMotion compared to Eodyne's solution is the large size of the device, which makes it unsuitable for certain spaces such as the home, and also increases the price considerably.

- GRIPABLE (UK) is focused on hand and wrist movement exercises through a hand-held device connected to an app to engage patients in fun therapy games. The start-up raised a significant amount of capital in 2022, which was invested into scaling up its clinical evidence and the distribution into the US market. Despite its small size and portability, which make GripAble suitable for home, it focuses primarily on improving grip strength, which is a narrow application domain as compared to RGS-E.

COMPANY	Diagnosis & Prognosis	Continuum of Care	Rehabilitation through consumer electronics	Target training				Scientific papers
Eodyne	✓	✓	✓	Motor	Cognitive	Speech	Affective	45+
Mindmaze	⊗	⊗	⊗	Motor	Cognitive			18
Swordhealth	⊗	⊗	⊗	Motor				2
Evolv Rehab	⊗	⊗	⊗	Motor	Cognitive			16
Rehametrics	⊗	⊗	⊗	Motor	Cognitive	Speech		20
Jintronix	⊗	⊗	⊗	Motor	Cognitive			8
Saebo	⊗	⊗	⊗	Motor	Cognitive			21
Tyromotion	⊗	⊗	⊗	Motor	Cognitive			34
BrainHQ	⊗	⊗	✓		Cognitive		Affective	26
Lumosity	⊗	⊗	✓		Cognitive			20
MiraRehab	⊗	⊗	⊗	Motor	Cognitive			10

Figure 8. Competition analysis.

RGS COMPETITIVE DIFFERENTIATORS: Eodyne sets itself apart by advancing a disruptive approach to neurorehabilitation that integrates diagnosis, prognosis, and intervention in a single process for patient care and management. This approach is targeted at improving patient outcomes and getting faster and longer lasting results that will get patients discharged sooner and keep them out of the hospital by reducing readmissions. Moreover, the RGS-E solution is delivered through affordable consumer electronics already present in most patient homes, such as PCs, smartphones, and smartwatches, which lowers the purchase barriers. **Below we list our competitive differentiators and barriers for competitors:**

1. **Alignment with patient journey**: The RGS-Ecosystem is strategically aligned with the patient journey, offering a seamless transition from hospital to home. By utilizing familiar consumer electronics, RGS-E reduces the learning curve for users and enables to fill the gaps between treatment phases, where currently patients are provided no treatment. This approach ensures that patients receive continuous support for rehabilitation and monitoring, and early supported discharge, minimizing the risk of readmissions. The system's design takes into account the diverse stroke care landscape across Europe, addressing disparities in stroke management and care. This alignment with the patient's journey fosters a holistic and patient-centric approach to neurorehabilitation, ultimately improving the overall quality of care.
2. **Reduced costs of care :** Eodyne's RGS-E sets a new standard in post-stroke neurorehabilitation by significantly lowering costs associated with treatment and readmissions. Leveraging existing consumer electronics already present in patients´ homes, the RGS-E solution eliminates the need for hospitals to make substantial investments in specialized equipment for telemedicine deployment. This approach not only reduces the financial burden on healthcare institutions associated to treatment, but also prevents the deterioration of patients to significantly reduce readmissions. By expediting patient recovery and shortening outpatient treatment lengths by 40%, and reducing readmissions rates from 44% to 26%, RGS-E can potentially save up to €4.603 per patient which translates to cost reductions of €8.9 billion in the EU and US based on incidence.
3. **Increased scalability**: RGS-E introduces a highly scalable solution to post-stroke neurorehabilitation, unlocking the potential for widespread access and treatment volume. By utilizing affordable and widely available consumer electronics, the system eliminates barriers to entry for hospitals and facilitates the deployment of

telemedicine solutions at scale. The integration of telerehabilitation allows patients to train autonomously at home, tripling the volume of therapy delivered. Simultaneously, therapists can efficiently manage more patients by leveraging digital tools for remote assessment, monitoring, and prescription. This increased scalability not only enhances patient outcomes but also optimizes the efficiency of clinical resources, offering a transformative impact on treatment capacity.

Shortly after the Russia-Ukraine war outbreak, Eodyne started providing Ukraine its telerehabilitation software as healthcare aid. Currently, more than 50 hospitals and rehabilitation centres in Ukraine are using our products. This is clear proof of the scalability potential of RGS-E that shows these solutions can be rapidly deployed and adopted with minimum resources. We have attached a Memorandum of Understanding with the Ministry of Health of Ukraine in the Annex.

4. **Data integration across patient journey phases:** Eodyne is in a unique position by integrating data across all phases of the patient journey, from admission and inpatient treatment to outpatient and post discharge rehabilitation and follow-up. The RGS-E platform continuously collects and analyzes data to estimate and update diagnosis to prognosis throughout the intervention process. This comprehensive approach not only enhances the precision of treatment but also provides valuable insights into patient recovery dynamics. Eodyne is the first among its competitors to advance a solution that integrates intervention with patient models for diagnosis and prognosis. RGS-E will provide therapists with continuous assessments built into the training activities that capture the complex dynamics of recovery, as opposed as relying in single, sparse clinical assessments at the hospital. Eodyne establishes a barrier for competitors by seamlessly integrating diagnosis, prognosis, and intervention within a single platform. This holistic approach ensures a comprehensive and unified solution for patient care, setting Eodyne apart in the field of neurorehabilitation.
5. **Scientific Evidence: Eodyne distinguishes itself through its strong scientific foundation and expertise in the field of computational neuroscience and neurorehabilitation**. As a spin-off company of SPECS research lab, we leverage decades of scientific research and have a solid track record with over 45 publications showcasing the clinical effectiveness of our solutions (Free Annex). This science-based approach is highly valued by clinicians and healthcare professionals, as it provides them with confidence in the efficacy of our products. Moreover, Eodyne's portfolio of rehabilitation and monitoring solutions is boosted by the ongoing research addressing the full spectrum of stroke symptomatology, which sets us apart from competitors addressing single rehabilitation domains and thus force customers to rely on several products.

SWOT ANALYSIS

Below is a SWOT conducted to help us to identify internal and external factors that are favourable and those that represent a drawback.

Table 3: SWOT Analysis

Opportunities	Threats
- Emerging, high potential, and growing market. - Millions of people require rehabilitation and products like RGSclinic, RGSapp, and RGSweb. - Proven interest from a large number of specialized rehabilitation centers and patients. - eHealth: facilitating transfer from the hospitals/ day centers to home supporting a "soft landing" with continuous rehabilitation and monitoring. - Market drivers such as public budget constraints that force the search for more cost effective and efficient solutions. - Development of policies and directions at a global level that includes the incorporation of effective and science-based solutions.	-Typical low adherence to neurorehabilitation treatment. -Reluctance to adopt new technologies from professionals and elderly patients. -Fragmented competitors: emerging market with various companies trying to reach the market and to position themselves. -Long purchase processes in the public sector -Inertia in medical health systems. -Lengthy and costly processes required for the certification of medical devices class 2a and above. -Large variability in treatment guidelines and reimbursement models across Europe
Strengths	**Weaknesses**
- Clinically validated with over 300 patients in Spain, France, Sweden, and Germany. - Accessible and low-cost technology: Hardware consists of standard PC, motion capture, Internet connection, and low-cost wearables. - Low-cost software distribution with high scalability.	- The development of new clinically validated protocols takes up to 6 months. - Eodyne´s commercial visibility comprises mainly Spain and The Benelux. - Eodyne team and experience is mostly technological, with a smaller portion having

- Innovative, science and IT-based technology developed by a recognized leading international research group. - Combined know-how in science, product development, and commercialization process. - Reduces costs of staff, hospitalization, and infrastructure at hospitals by allowing rehabilitation at home. - Manufacturer of Medical Devices License by the Spanish Agency for Medicines and Medical Devices (AEMPS) that allows us to auto-certify medical devices Class 1. - Ongoing collaborations with large industry players such as Medtronic and Roche Diagnostics. - Hybrid commercialization model utilizing direct salespeople to support established distributors will leverage distributors existing relationships with customers and sales and marketing power to drive adoption into the market, improving scalability within and across geographic markets.	experience in business development and sales. - Lack of experience in the certification of medical devices beyond Class I - Lack of know-how in advanced cyber security compliant with GDPR for digital health solutions

5. TEAM AND MANAGEMENT

Table 4: Team members

Team Member	Gender	Founder	Position	Key competences	Commit.
Santiago Brandi	Male	NO	CEO	Strategic planning, product development, management, leadership, commercialization	100%
Gerónimo Galíndez	Male	NO	CFO	Operation, Financial and Project management and coordination.	100%
Sergi Ramirez	Male	NO	Development lead	Software development, team leadership, technical planning, standards.	100%
Sergio Gómez	Male	NO	Technical coordinator	Technical integration, processes, quality	100%
Joel Blasi	Male	NO	Designer leader	2D and 3D modelling, animation, user experience, graphic interfaces	100%
Imen Hamdani	Female	NO	Quality control responsible	Quality control coordination activities	100%
David Nery	Male	NO	Full stack developer	Back-end developer	100%
Aarushi Sharma	Female	NO	Project Manager	Project organization, documentation, time task controller.	100%
Mario Rodriguez	Male	NO	Programmer senior	Software production.	100%
Lluis Garcia	Male	NO	Programmer senior	Software production.	100%
Rajsuryan Singh	Male	NO	Engineering	Machine learning, computer vision	100%
Hanaa Kilouli	Female	NO	Business developer	Commercialization leader	100%
Ester Aran	Female	NO	Administrative	Administrative tasks	100%
Paul Verschure	Male	YES	Scientific advisor	World leader in neurorehabilitation research, professor of neuroengineering	10%

RELEVANT ACHIEVEMENTS AND EXPERIENCE. Since Eodyne's creation in 2014, our team has gained significant expertise in technology transfer, development, validation, and commercialization of neurorehabilitation technologies linked to the long track record of SPECS-lab's research. Most of the team members, including software and business developers, have been in the company working together for many years and have a very deep knowledge of the technology and its end users.

Over the past few years, **Santiago Brandi, Eodyne' CEO**, has personally visited public hospitals, rehabilitation clinics, patients' associations, and patients in their own homes across several countries, including Spain, Portugal, the UK, the Netherlands, Germany, Switzerland, Italy, Belgium, Sweden, and France. In these visits, Santiago engaged with over 400 healthcare providers, rehabilitation professionals, and patients, including neurologists, rehabilitation doctors, occupational therapists, physiotherapists, and speech therapists, to understand the needs and pain points of end users. This first-hand knowledge serves as a foundation for Eodyne's efforts to develop innovative technology solutions that address these needs, empower healthcare professionals, and ultimately improve the lives of patients undergoing rehabilitation.

Santiago Brandi and Eodyne's CFO, Geronimo Galindez, have negotiated a significant contract with Roche Diagnostics. This partnership aims to provide Eodyne's telerehabilitation services to stroke patients at Hospital Bellvitge (Barcelona, Spain) following their discharge. The agreement reflects Eodyne's commitment to extending the reach of their innovative solutions beyond the hospital setting and into the realm of post-discharge care. This partnership not only demonstrates Eodyne's dedication to improving patient outcomes but also highlights their strategic vision in forging key collaborations to expand the delivery of high-quality rehabilitation services.

Under the leadership of Santiago and Geronimo, **significant milestones have been achieved** in obtaining regulatory clearances and certifications for the company's innovative products. Eodyne has obtained a Manufacturer of Medical Devices License from the Spanish Agency for Medicines and Medical Devices (AEMPS). This license showcases Eodyne's commitment to complying with rigorous quality and safety standards in the development and manufacturing of medical devices. In addition, we have prepared the corresponding dossiers and obtained the FDA and CE mark certification as Medical Device Class 1 for RGSclinic, as a product for motor rehabilitation after stroke.

MISSING SKILLS. To successfully execute our technological and commercial plans, we have identified the following key positions and skills we will need to add:

- **International commercial skills:** Experience scaling businesses in the digital rehabilitation markets in Europe and the US. To fill this gap, we will hire a commercial director with proven experience in the international commercialization of medical devices to build and train the sales team and build the distributor network.
- **Quality and regulation expertise:** Knowledge in medical and data related regulations across Europe including MDR, GDPR, QA, ISO, certification of medical devices Class 2a and above, reimbursement systems (e.g., DigA/Germany, PEC-AN/France). To fill this gap, we have hired a technical coordinator with experience in MDR, FDA and ISO, and are working with the consultancy company, Ingecal, who is providing training to the technical team to build in-house know-how. Additionally, we expect to hire regulation specialists in the target markets at later stages of the project.
- **Technological know-how**: Knowledge in data management and cybersecurity for medical devices to properly handle health data across all technological platforms (ie, web, mobile, desktop). To address this need we will work with consultants, train our technical team, and carry out technical audits.
- **Healthcare Systems:** Knowledge of stroke management differences across European countries, such as standard of care, periods for inpatient, outpatient, and home-based treatment phases, standard clinical assessments, costs, and reimbursement schemes. We will subcontract clinical partners (i.e., Hospitals) in each target location that will deliver the required know-how. We are already collaborating with Parc Sanitari Sant Joan de Deu (Barcelona, Spain), University Hospital of Limoges (Limoges, France), Sint Maartenskliniek (Nijmegen, The Netherlands), Charite University Hospital (Berlin, Germany), and the National Institute Rest and Care for the Elderly -INRCA- (Ancona, Italy), among others.

GENDER BALANCE. Eodyne declares its commitment to the establishment and development of policies that integrate **equal treatment and opportunities between women and men**, without discriminating directly or indirectly based on sex, as well as in the imposition and promotion of measures to and promotion of measures to achieve real equality within our organization, establishing equal opportunities between women and men as a strategic principle of our Corporate Policy.

As a strategic principle of our Corporate and Human Resources Policy, according to the definition of the Human Resources Policy, in accordance with the definition of this principle established by the Organic Law 3/2007, of March 22, for effective equality between women and men. At the moment, **32% of our staff are female**, we plan to hire more women by attending specific job fairs or conferences addressed to women. It is in our policy to respect EU policies and guidelines concerning equal opportunities during the project execution. We are committed to establish measures and objectives for strategic engagement for gender equality to promote the advancement of women.

EMPLOYEE RENTENTION ACTIVITIES. Eodyne's diverse team is nurtured and retained through a combination of professional development opportunities, flexible work arrangements, a culture of excellence and passion, and a strong emphasis on their mission of improving patients' lives. By creating an inclusive and supportive environment, Eodyne harnesses the collective talents of their diverse team to drive innovation and make a positive impact in the field of healthcare technology. Furthermore, Eodyne's founders and managers have a history of working closely together, having known each other for more than a decade and collaborating on previous successful projects. This long-standing relationship built on trust and familiarity contributes to a cohesive team environment, enabling members to rely on each other's strengths and work together effectively towards common objectives. To further incentivise and align the team**, Eodyne has implemented an Employee Stock Ownership Plan (ESOP) agreement**. Non-founding managers and employees are given a significant stake in the company's achievements through an equity-based incentive plan, which includes 15% of the company's common stock. This ownership stake not only aligns their interests with the company's long-term growth but also serves as a concrete acknowledgment of their contributions.

COMPANY GOVERNANCE AND CAP TABLE. **Eodyne's governance structure** is designed to combine a diverse array of expertise in driving the company's vision forward. The Board of Directors includes Santiago Brandi, as CEO, who offers leadership honed through years of navigating the complexities of the healthcare industry, Geronimo Galindez, as CFO, who provides extensive financial and administrative experience to overview operations, and Professor Paul Verschure, Eodyne's founder, who brings cutting edge insight into neurorehabilitation and brain plasticity principles,

Complementing the Board are our key advisors, each contributing specialized knowledge and perspective. Todd Snowden, with his extensive background in healthcare executive roles and strategic consulting, lends invaluable insights into market dynamics and business strategy. Dr. Per Hamid Ghatan, leveraging his expertise in brain injury rehabilitation and occupational health, guides Eodyne on clinical matters and market uptake, ensuring the alignment of products with real-world healthcare needs. Dr. Anna Mura, with her proficiency in multidisciplinary education and scientific communication, enriches Eodyne's outreach efforts, enhancing user experience and stakeholder engagement.

Collectively, this governance framework ensures that Eodyne benefits from a wealth of expertise spanning neuroscience, healthcare management, market strategy, communication, and user experience. Each member plays a defined role, contributing to the company's success by providing strategic direction, financial proficiency, clinical insights, and effective communication strategies. Their collective wisdom and guidance serve as a cornerstone in Eodyne's journey towards pioneering advancements in neuro-technological solutions.

Eodyne's CAP Table includes private partners and the involved research and education institutions. Paul Verschure is the majority shareholder with 81.069% of shares, Carme Buisan holds 4.765% of shares, and the institutions Universitat Pompeu Fabra, Institució Catalana de Recerca i Estudis Avançats, and the Institute for Bioengineering of Catalonia each hold 4.722% of shares.

6. MARKETING AND SALES PLAN

BUSINESS MODEL

KEY ACTIVITIES. Hospital visit and direct sales, workshops and webinars, focus groups, free demos and trials, networking and participation in events, press releases and newsletters, social media campaign, user-friendly website and SEO optimization, webinars, marketing content development (blog posts, articles, videos, infographics related to stroke recovery, flyers, banners), demonstrations and workshops for stroke patient associations and professionals' (e.g., occupational therapists, neurologists) associations, leverage customer reviews and testimonials and participation in European and national projects collaborating with KOLSs and reference clinical and industrial partners.

By engaging in these key activities, Eodyne aims to raise awareness our stroke rehabilitation solutions and scientific approach, build relationships with healthcare providers, educate clinicians and therapists, gather valuable feedback, and ultimately drive sales and adoption of their products. These activities are essential for establishing a strong market presence, expanding the customer base, and advancing our mission of improving patients' lives through innovative technology.

RESOURCES. Our resources:
- More than 45 scientific publications that show the clinical efficacy of our approach to neurorehabilitation.
- Experienced team with several backgrounds working together for many years.
- Multiplatform approach to cover the whole patient journey
- CE mark as MD Class 1 and FDA approval for one motor rehabilitation product
- Collaborations with dozens of the most prominent hospitals and universities in Europe
- More than 3M€ in public funds raised for technology development between 2022 and 2025
- A customer list with more than 800 contacts including patients, hospitals, rehabilitation clinics, neurologists, innovation managers, occupational therapists, physiotherapists, and speech therapists.

CUSTOMER RELATIONSHIP Eodyne emphasizes a customer relationship approach that is close, personalized, and fosters continuous feedback loops. We prioritize maintaining strong relationships with customers to better understand their needs, challenges, and preferences. Eodyne actively seeks customer feedback and incorporates it into the product development roadmaps. By continuously engaging with customers and listening to their input, Eodyne ensures that their solutions are aligned with market demands and evolving customer requirements. This feedback loop allows them to iterate and improve their products over time, enhancing their effectiveness and addressing specific customer pain points. Most importantly, Eodyne will work with payers and hospitals to ensure continuity of care from hospital to outpatient to home.

SALES CHANNELS. We will follow a **hybrid commercialization model** utilizing direct salespeople in our different markets to support established distributors. By doing this, we will leverage distributors' existing relationships with customers and sales and marketing power to drive adoption into the market, improving scalability within and across geographic markets. Eodyne will establish local commercial teams to actively manage, support, and motivate distributors through regular communication and feedback, training, marketing support, sales support, incentive programs, and customer service support. Moreover, through continuous improvement of our products and development of new features, we will provide distributors opportunities to frequently reach out to their customers.
We will look for distributors where there is product synergy with other products in their portfolio, that are **service-oriented** with experience introducing change of behavior products to the market, and that are able to provide customer support and to convey the value of the RGS products. We expect distributors to be responsible for the sale and post-sales process, software installation, setup, training, and first level customer support. Eodyne will take care of second level support that may involve complex technical issues. We expect distributors to be closely involved with customers, therefore, we estimate commissions of approximately 40%. We will look for **distributors with the following profile**: **(i) National Coverage,** to ensure our products reach a broad audience of potential customers, including rehabilitation centers, clinics, hospitals, and individual practitioners, **(ii) Existing Relationships with Customers** including hospitals, clinics, occupational therapists, speech therapists, neurologists, and rehabilitation specialists, **(iii) Understanding of Rehabilitation Practices**, familiarity with the challenges faced by healthcare professionals and patients in neurorehabilitation, and ability to effectively communicate how our products can address these needs**, (iv) Technical Competence,** to understand and demonstrate the features and capabilities of Eodyne's products and to provide training and support, **(v) Post-Sales Support Capabilities,** with the infrastructure and resources to provide comprehensive post-sales support to customers, and (vi) **Marketing and Promotional Abilities**, to effectively market Eodyne's solutions to their network of customers. They should be capable of organizing promotional events, conducting product demonstrations, and generating awareness about our products.

In Europe, distributors of rehabilitation products with these characteristics are for example Rölke Pharma (Germany), h/p/cosmos (Germany), and Hankamp Rehab (The Netherlands). There are also larger, more generic distributors of assistive and healthcare products that are a potential a fit for Eodyne's products, such as Netraco & Santé (France) and MD Innovation (UK). In the US, specific distributors include Accelerated Care Plus (ACP), DIH Technology, and North Coast Medical (NCM) and among the larger, generic distributors we find Medline

Industries, Cardinal Health, McKesson, Direct Supply, and Americorp Financial. We will engage with distributors with these qualities who can effectively reach our target markets, build credibility for our brand, and ensure the successful adoption of RGS-E. To continuously support and motivate our distributors, Eodyne's sales team will focus on the following activities:

- **Training and Education:** We will provide comprehensive training sessions to distributors on the RGS Ecosystem and its components. We will transfer in-depth knowledge about product features, benefits, and applications to effectively communicate with potential clients.
- **Marketing material**: We will develop tailored marketing materials such as brochures, presentations, and product demos that highlight the unique selling points and effectiveness of RGD-E. These materials will be tuned to each country to resonate with the specific needs and preferences of each target market.
- **Sales Support**: We will offer ongoing support to distributors by providing them with sales scripts, FAQs, and information about competitors. We will support them on sales visits and ensures that they are well-prepared to address inquiries, overcome objections, and close deals successfully.
- **Market Research and Insights**: Eodyne will continuously gather market data and insights to identify emerging trends, competitive landscape, and customer preferences in each target market. We will share these insights with distributors to help them tailor their sales approach and strategies accordingly.
- **Networking and Events:** We will participate with distributors in relevant industry events, conferences, and trade shows such as MEDICA, REHACARE, Neuro Convention, European Stroke Organization Conference (ESOC), VR4REHAB, World Congress for Neurorehabilitation, European Congress of Neurorehabilitation, Digital Health World Congress, and Digital Health Week, among many others. These platforms provide valuable opportunities for distributors to showcase our solutions, engage with potential clients, and build partnerships with key stakeholders.
- **Feedback and Improvement:** We will encourage distributors by providing feedback on product performance, customer experiences, and market dynamics. We will also pursue the continuous improvement of our products to facilitate the sales process and provide distributors opportunities to reach out to customers with novel features.

The key aspect of our sales approach will be to focus on the **TREATMENT CONTINUUM**. A crucial differentiator of the RGS-E approach is the alignment with the patient journey. RGS-E smoothens the discharge process and the transition from hospital to home by using familiar consumer electronics and reducing learning curves. Therefore, we expect hospitals to leverage RGS-E to provide early supported discharge services, including continuous support, intervention, and monitoring to minimize the risk of readmissions after discharge. Therefore, we will work with payers, providers, and patients, to ensure **continuity of care** from hospital to outpatient to home. To do so, we will put emphasis in **education and awareness**, providing clear information about the benefits of continuing rehabilitation with RGS-E after outpatient treatment ends. We will highlight how the technology can continue to support the recovery journey and improve patients' quality of life and reduce readmissions. We will leverage our diagnosis and prognosis algorithms to explain patients how their health and functional recovery could potentially improve or deteriorate based on their own data.

COSTS AND REVENUES

Our main costs include, **Personnel**: Business development team, Technical Support team, Management, and **Operating expenses**: Cost of sales, Marketing, Cloud infrastructure Housing, services, and outsourcing.
Our revenue model is SaaS, with an approximated monthly revenue per patient of 24€, adjusted for each market. The assumptions and detailed projections for costs and revenue in the first 6 years of commercialization are shown in Section 8

GO-TO-MARKET PLAN

First, we will conduct comprehensive market studies to validate and refine our assumptions in terms of market, pricing, and regulations. This step will help us shape our strategies accordingly. Second, we will prioritize clinical validations and obtain CE and FDA certifications for our products, ensuring they meet the necessary quality and safety standards for reimbursement. Simultaneously, we will establish dedicated sales teams to lead our outreach efforts through a hybrid commercialization model utilizing direct salespeople in our different markets to support established distributors. We will develop distribution channels to address the US and main European markets. Initial focus will be on the private sector, where purchases are usually less constrained by bureaucratic processes and sales tend to be faster. In parallel, we will work on obtaining reimbursement on the different

markets, prioritizing markets with favorable legislation, such as the DiGA and PECAN frameworks in Germany and France, respectively, to facilitate access and penetration of crucial markets. Key to the commercial uptake will be the careful selection of appropriate distributors and the continuous management and support of these distributors through our local sales teams. Figure 9 illustrates the phases and milestones of our go-to-market strategy.

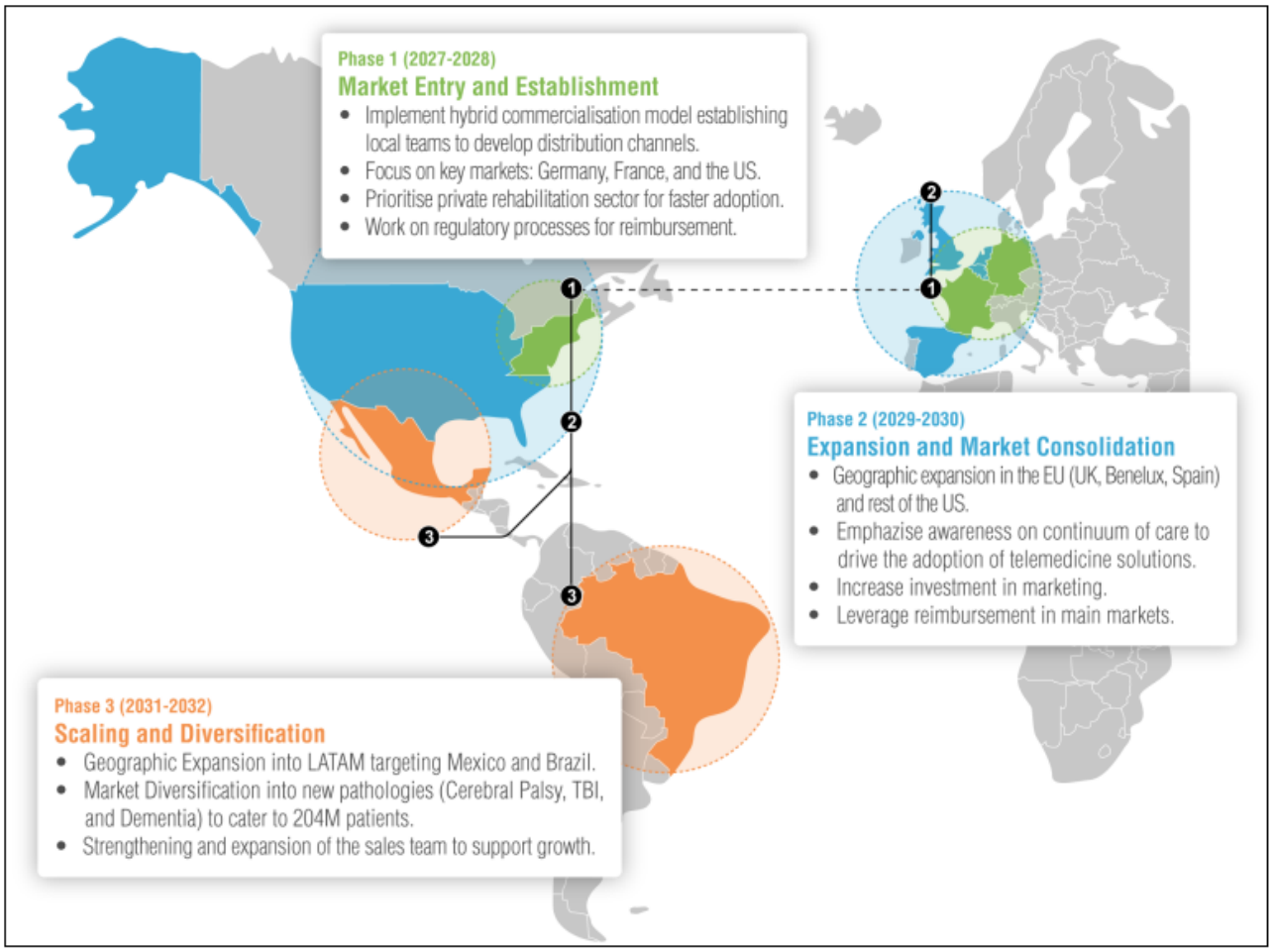

Figure 9: Go-to-market phases.

PHASE 1 (2027-2028): MARKET ENTRY AND ESTABLISHMENT. Objective: Establish a foothold in key markets (Germany, France, USA) and develop initial distribution channels.

Key Steps:

- Sales Team Development: Hire an experienced Sales Director to lead international expansion efforts.
- Commercialization Model: Implement a hybrid approach, establishing local teams in target markets.
- Market Focus: Prioritize Germany, France, and the USA due to favorable legislation and market conditions.
- Distribution Network: Create teams of 2 to 3 business developers in each market (more in the US) to actively manage and support distributors.
- Market Penetration Strategy: Begin with private rehabilitation sector due to faster decision-making processes.
- Reimbursement Planning: Work on administrative processes for reimbursement in target markets.
- Collaborations: Partner with hospitals, insurers, and industry collaborators for evidence generation and market entry support.

Resource Allocation:

- Employ 19 people dedicated to commercial activities.
- Allocate €1,700,000/year to marketing.
- Outcome Expectation: Reaching 242 hospitals by the end of year 2.

PHASE 2 (2029-2030): EXPANSION AND MARKET CONSOLIDATION. Objective: Emphasize continuum of care and drive adoption of telemedicine solutions while expanding market presence.

Key Steps:

- Continuum of Care: Focus on education and awareness for continued rehabilitation post-discharge support to drive the adoption of telemedicine solutions.
- Marketing Boost: Increase marketing efforts, hire online marketing experts, and expand digital presence.
- Geographical Expansion: Address the UK market and continue expanding distribution networks in the EU and US.
- Sales Growth: Expect boosted sales in reimbursed markets, particularly Germany, France, and the USA.

Resource Allocation:

- Increase marketing expenditure to approximately €5,000,000/year.
- Grow commercial teams, expecting a total of 31 personnel by year 4.
- Outcome Expectation: Reach 729 hospitals by year 4.

PHASE 3 (2031-2032): SCALING AND DIVERSIFICATION. Objective: Further scale operations, penetrate new markets (LATAM), and expand into other pathologies.

Key Steps:

- Geographic Expansion: Enter LATAM market targeting Mexico and Brazil
- Market Diversification: Expand into other pathologies including Cerebral Palsy, TBI, and Dementia effectively increasing our target population from 81M to 204M patients.
- Product Adoption: Expect increased adoption due to expanded market reach and additional patient populations.

Resource Allocation:

- Grow commercial teams for a total of 45 salespeople by year 6.

Outcome Expectation: Reach 1635 hospitals by the end of year 6, with total sales revenue of approximately €52M.

MARKET ENTRY BARRIERS

Table 6. Summary of market entry barriers

BARRIER DESCRIPTION	MITIGATION STRATEGIES
SLOW PURCHASING PROCESSES (BUSINESS): Public hospitals have relatively slow purchasing processes, either because of annual budgets or because certain purchases are made through tenders. Therefore, entering this market segment may take a considerable amount of time.	1. Develop value propositions tailored to public health systems' needs. 2. Prioritize private hospitals initially. 3. Focus on countries with favorable legislation. 4. Offer low recurrent fees. 5. Participate in Public Procurements for Innovation (PPIs).
REIMBURSEMENT BARRIERS (REGULATORY): More and more, insurance companies in Europe require real-world evidence to consider the reimbursement of medical devices and services. Hence, trials in several countries are necessary to access the corresponding markets.	1. Collaborate with European partners for evidence generation. 2. Conduct trials in multiple countries.
HETEROGENEOUS LEGISLATION (REGULATORY): Regulation of healthcare markets operate differently from country to country and have different requirements for example in data management guidelines and quality standards.	1. Focus initial commercial efforts in countries with streamlined regulations. 2. Obtain necessary certifications for target markets. 3. Conduct market studies early in product development. 4. Collaborate with experienced partners like Medtronic and Roche Diagnostics.

AI ADOPTION IN HEALTHCARE (SOCIAL): The adoption of AI in healthcare is faced with a significant adoption barrier related to the lack of trust that stem from several factors, such as Lack of Transparency, Safety and Patient Outcome and Legal and Ethical concerns.	1. Design AI models for transparency and explainability. 2. Validate algorithms in real-world settings. 3. Adhere to European guidelines and legal frameworks. 4. Involve stakeholders in design and implementation.
RESISTANCE TO TECHNOLOGY (SOCIAL): Given the most common age range of stroke patients, they might be unfamiliar and resistant to new technology. Moreover, patients may have concerns about the safety and effectiveness of using AR/VR for their rehabilitation, especially if they have limited experience with it. Additionally, patients might be reluctant to go over the learning curve to use the technology.	1. Develop user-friendly technology. 2. Provide clear explanations and success stories. 3. Share testimonials from other users. 4. Collaborate with patients in development.
OVERBURDENED STAFF (CLINICAL): Healthcare professionals handling patients (Doctors and mainly, therapists) usually have little time to spare due to the high volume of patients visited daily, especially in public hospitals. Thus, there might be resistance to introduce new products in medical practice if they involve a learning curve and additional time for training and onboarding of patients	1. This weakness can be turned into an opportunity by focusing on how the technology can optimize the capacity of the clinical staff, allowing them to effectively monitor and manage more patients efficiently.

PRICING STRATEGY

We follow a SaaS revenue model that allows Eodyne to generate recurring revenue, which is crucial for the continuous improvement and expansion of our rehabilitation platforms, ensuring that we can stay competitive and provide ongoing updates and support to our customers.

On average, **the estimated revenue per patient/month is 24€**, with price adjustments per country. This pricing point has been determined considering various factors and references in the sector. One reference considered is the cost of a single occupational therapy session at home. Typically, such session can range between 50€ and 70€. Based on these prices, 12 home sessions of occupational therapy would cost between 600€ and 840€, while the RGS Ecosystem offers a 24€ flat fee for unlimited sessions per month. This makes our products accessible to a broader population, allowing individuals to engage in continuous rehabilitation without the financial burden associated with private rehabilitation sessions.

Another important consideration is the potential savings in readmission costs. In Europe, readmissions for stroke patients average around 19,400€, with variations based on health complications. Furthermore, research indicates approximately 44% of stroke patients are readmitted within six months after discharge. However, studies have shown that providing continuous support, with early supported discharge and home-based interventions can significantly reduce readmissions rates down to 26%. With this in mind, we have selected a low-price, high-volume pricing strategy that can reduce purchase barriers (e.g., public tenders) and help hospitals significantly reduce readmission costs.

Our target customers include rehabilitation centers such as public hospitals, private clinics, and patient associations. For large institutions, we anticipate implementing volume discounts when many patients are treated. Furthermore, the purchase processes of public hospitals are typically not aligned with monthly variable payments. To address this, we will offer closed packs that hospitals can incorporate into their annual budgets and cover with a single payment. These packs can be renewed and adjusted annually based on projected patient volumes. Additionally, recognizing that patients require clinical guidance and support, we will establish an in-house clinical team comprising rehabilitation professionals such as occupational therapists. This clinical support service will be available to users who have been discharged from the hospital. We strongly believe that this service will incentivize the uptake of our solutions and enhance treatment adherence.

In summary, our pricing strategy aims to strike a balance between affordability for patients and the long-term sustainability and development of our rehabilitation platforms. By considering industry references and the potential cost savings associated with our solutions, we have established a pricing structure that promotes accessibility, encourages continuous rehabilitation, and provides a valuable return on investment for our customers. **We include LOIs from potential customers, commercial partners, and distributors in the annex**: Hospital Vall de Hebron, University Hospital of Limoges, Institute for Functional Recovery La Salle, Medtronic Iberica, and Hankamp Rehab.

SCALE UP POTENTIAL

Our scalability is underpinned by 3 core pillars:

1. **HYBRID COMMERCIALIZATION MODEL:** This approach involves establishing small local commercial teams in different markets to support established distributors. By leveraging existing distributor relationships and sales and marketing capabilities, this model aims to drive adoption into the market, improving scalability within and across geographic regions. Eodyne will ensure effective management, support, and motivation of distributors through regular communication, feedback, training, marketing support, sales support, incentive programs, and customer service support.
2. **SCALABLE TECHNOLOGY:** We aim to transform consumer electronics, such as smartphones and smartwatches, into tools for stroke intervention, diagnosis, and prognosis, targeting cognitive, motor, and speech rehabilitation. By providing scalable and affordable solutions aligned with patients' needs throughout their journey, this approach aims to fill gaps in care, support transitions and discharge, and leverage valuable data for clinical insights. Developing interactive technology that doesn't rely on dedicated equipment, such as infrared cameras or inertial sensors, allows for software-only solutions, making them much more scalable than hardware-based alternatives.
3. **MARKET DIVERSIFICATION:** The principles for neurorehabilitation and brain plasticity behind RGS-E are transversal and potentially applicable to several pathologies such as Traumatic Brain Injury, Chronic Pain, Alzheimer's, Cerebral Palsy, Multiple Sclerosis, Parkinson's disease, and Spinal Cord Injury, significantly expanding our target patient population. Adapting the solution to cater to these additional pathologies not only increases the potential market size to more than 306 million patients but also enhances product placement per hospital, drives market scaling, and boosts market penetration.

7. RISKS

Table 7. Description of main project risks

Description of risk (Likelihood/Severity)	Proposed risk-mitigation measures
DELAY IN CE MARKING IN EUROPE (MEDIUM/MEDIUM): Diagnosis and prognosis tools will likely require MDR certification under Class 2a or above. This process is lengthy and costly, and the notified bodies involved have seen an increase in demand due the MDR updates. A delay on this process would delay our entry into the market	Eodyne counts with a Manufacturer of Medical Devices License by the Spanish Agency for Medicines and Medical Devices (AEMPS). Additionally, we already count with the support of a consultancy company specialized in quality and regulation in healthcare, Ingecal, to prepare for the certification process.
HIGH COMPETITION INTENSITY (MEDIUM/HIGH): The telerehabilitation markets experienced a boom due to the COVID-19 crisis and several new competing solutions have emerged. We expect and intense competition that will difficult market penetration.	We have a highly differentiated product covering the entire patient journey with extensive clinical evidence that protects our position with current product offerings and in front of newcomers. Additionally, we collaborate in research and innovation projects and continuously integrate the latest technologies in the fields of AR/VR, computer vision, and AI among others to maintain a scientific and innovative advantage
LOW ADHERENCE (HIGH/HIGH): Many stroke patients struggle with lack of motivation and even depression, thus, adherence to neurorehabilitation is a known challenge. Additionally, the elderly population is not	We will implement several mitigation measures to address this risk. First, the training scenarios are gamified to increase engagement. Second, we will provide tools for communication between therapist and patient that will facilitate efficient monitoring, including automatic low-

always the most enthusiastic about adoption of new technology. As a result, therapists might struggle to make patient adhere to training programs using our technology at home. This could also result in a high number of dropouts during the clinical trials.	adherence alerts for professionals. Third, we will focus on creating intuitive and friendly application to maximize user experience, including several educational tools, such as embedded instructions and video tutorials. Fourth, we will implement an AI-based virtual coach to increase patient motivation and adherence.
COMPLEX REIMBURSEMENT PROCESSES (MEDIUM/MEDIUM): There have been significant initiatives in Europe to fast-track market access for Digital Therapeutics (DTx) and digital health products by facilitating reimbursement (e.g., DVG/DiGA in Germany, PECAN in France). However, getting into these programs is not a simple process; clinical evidence must be generated in the local healthcare systems and must follow country-specific guidelines in terms of quality and data management guidelines, besides requiring all documentation to be delivered in local language. Therefore, we time to market might be in risk.	We have several measures to reduce this risk. First, we will engage with regulatory experts familiar with the requirements and guidelines of each country's healthcare system. Second, we will establish local partnerships with healthcare providers, research institutions, or technology partners with experience in navigating the local regulatory landscape. Finally, we will conduct clinical trials and generate robust clinical evidence within the local healthcare systems. Adhering to country-specific guidelines regarding quality, data management, and language will strengthen our case for reimbursement and market access.
LOSING TALENT (MEDIUM/MEDIUM): The risk of losing talent for SMEs in our sector can be significant because the tech industry is highly competitive, with many companies looking for skilled professionals. Larger corporations normally offer attractive compensations, making it challenging for SMEs to compete in terms of salary and benefits. Additionally, SMEs in the tech sector may not have the same level of brand recognition and reputation as established industry players. Losing key people on the team could have a negative effect on the technology development timeline.	Being an SME, we can provide competitive compensation packages including for example, stock options. We also offer flexible work arrangements, including remote work options, which have become increasingly important in the post-pandemic work environment. Additionally, we promote a positive company culture that prioritizes employee well-being, and open communication and we make emphasis in our mission, which is focused on making a meaningful impact on patient lives.

REGULATORY REQUIREMENTS. In the European Union, medical devices are regulated by the Medical Device Regulation (MDR) 2017/745, which sets out the regulatory framework for the development, manufacturing, and commercialization of medical devices. Eodyne ensures that their products comply with the MDR and follow the required processes for conformity assessment, including clinical evaluations, risk management, and post-market surveillance.

Eodyne also considers other applicable EU legislation and standards that may affect its activity, such as:

- General Data Protection Regulation (GDPR): As Eodyne deals with patient data, we must ensure compliance with GDPR regulations to protect the privacy and security of personal data.
- ISO 13485: This international standard specifies requirements for a quality management system specific to the medical device industry. Eodyne strives to meet the requirements of ISO 13485 to ensure the quality, safety, and efficacy of their products.
- ISO 20701: The international standard that establishes the requirements for implementing, maintaining, and continuously improving an Information Security Management System (ISMS). Eodyne is improving its system to protect information confidentiality, integrity and availability.
- Harmonized Standards: Eodyne may need to comply with specific harmonized standards applicable to medical devices, which provide technical specifications and requirements for product safety and performance.

To ensure compliance with ISO 13485, ISO 20701, and GDPR, as well as obtain and maintain the CE marking and obtain FDA approval for our products, several tasks and measures need to be implemented:

- Well-defined SLA: Create a comprehensive Service Level Agreement (SLA) that outlines the terms and expectations for service provision, quality standards, and regulatory compliance. This document will serve as a reference point for both internal teams and external stakeholders.
- Cybersecurity enhancements: Strengthen the cybersecurity measures within Eodyne products' platforms and communication to protect sensitive data and ensure the integrity and confidentiality of patient information. This may include implementing robust firewalls, encryption protocols, access controls, and regular security audits to identify and address potential vulnerabilities.
- Customer support and ticket management system: Develop a dedicated customer support system that includes a ticket management system. This will allow for efficient recording, tracking, and resolution of customer incidents or inquiries. Ensure that all customer interactions and data are handled in compliance with GDPR regulations.
- CE marking maintenance: Continuously monitor and assess compliance with the relevant EU directives and regulations to maintain the CE marking of our products. This involves regularly reviewing and updating technical documentation, conducting conformity assessments, and adhering to post-market surveillance requirements.
- FDA approval: Develop a comprehensive plan and dossier to obtain FDA approval for the RSG Ecosystem. This includes understanding the specific regulatory requirements set forth by the FDA, conducting necessary preclinical and clinical studies, preparing, and submitting regulatory submissions, and collaborating with the FDA throughout the approval process.
- Documentation and record keeping: Establish a robust documentation system to track and maintain records of compliance activities, including risk management, quality management, and regulatory documentation. This ensures transparency and provides evidence of adherence to ISO 13485 and regulatory requirements.

8. FINANCIAL PLAN

The Income statement forecast displayed in Table 8 is based on the **FOLLOWING ASSUMPTIONS:**

1. The Sales revenue forecast is focused exclusively on the stroke market during the first 4 years of commercialization. Sales in the markets of Cerebral Palsy, TBI, and Mild Cognitive Impairment and Dementia start in year 5.
2. The income streams consist of three components:
   - Sales revenues from the RGS Ecosystem products.
   - Consulting income associated with specific potential projects developed for private partners.
   - Grants income, considering Eodyne's historical track record of research and innovation projects.
3. Sales revenue is forecasted on a bottom-up basis, considering each RGS solution and target country. This approach considers specific market parameters and characteristics, such as number of hospitals and stroke prevalence, aligned with Eodyne's market and product introduction strategy.
4. The average pricing of the different RGS solutions depends on the specific target markets. The placement of RGS products is influenced by factors such as target segment, price, and sales channel. Sales revenues in in 2027 focus on our main target markets, namely Germany, France, and specific regions in the US. Expansion across Europe and the US is projected in the following years, and LATAM markets are addressed starting year 5.
5. The costs of sales include distributor commissions, sales trips, and incentives for distributors and sales partners. During the initial two years of commercialization, the cost of sales is estimated at 50% of sales revenue, going down to 45% and 35% in years 3 and 5, reflecting a streamlined sales process, the acquired commercial experience, and improved market positioning for negotiating favorable distribution deals.
6. Eodyne's full-time equivalents (FTEs) are projected to increase in correlation with sales growth, considering certain scale effects. The FTE increase is primarily driven by additional sales, marketing, and business development roles, followed by product development FTEs.
7. The sales generated per person in the commercial team will increase over time due to factors such as improved sales experience, consolidated company positioning, reimbursement progress, product maturation, and increased investment in marketing. We estimate that the number of hospitals closed per Eodyne's salesperson will grow from 10 to 13 in the first 4 years of commercialization.
8. Base prices for each product are assumed as follows (with price adjustment per country):
   - RGSapp and RGSwear: 20€ per patient/month
   - RGSclinic: 3.000€ per year (Unlimited number of patients)
   - Diagnosis and prognosis service: 8.000 per year (Unlimited number of patients)

9. Averaging all products and adjusting for placement ratios, we estimate a total monthly revenue per patient of 24€.
10. We have assumed that the diagnosis and prognosis service sales will start on the second year of commercialization, and that will be adopted by 25% of our customers, growing to 33% by year 6.
11. We expect the adoption of our telerehabilitation products to increase as the Telemedicine market continues to grow and we emphasize the continuum of care. By year 6 we expect that each hospital will treat on average 114 patients at home with RGS-E per year. We estimate that in average patients will use RGS-E for 6 months after hospital discharge.
12. Overhead costs are directly correlated with the size of the organization as 35% of total wages in 2027 and 2028, reflecting costs for setting up offices and teams, to decrease to 30% and 20% in the following 4 years, reflecting streamlined operations of improved overall efficiency of the company processes.
13. The Telemedicine market is expected to continue growing, driving an increase in sales of RGS portable solutions like RGSapp and RGSwear.
14. The annual churn rate for hospitals and rehabilitation clinics is estimated at 5%, indicating the percentage of customers lost each year.
15. The total number of addressable rehabilitation centers (including hospitals, private clinics, and associations) is calculated as half of the total number of public hospitals in each country, based on market insights from Eodyne.
16. The projections assume capital investments of 6.3M€ in year one of commercialization to establish sales teams, offices, and distribution channels in our main markets in the EU and the US, and 5.8M€ in year three to accelerate the scale-up and gain market share. By year six we expect to reach 1.635 hospitals and 186.206 patients which represents approximately 5% of all patients in need of rehabilitation in our target markets.
17. The break-even point is anticipated to be reached in year three of commercialization. However, the projections show a negative balance on this year, reflecting the investment in marketing and growth of commercial teams to accelerate sales to be covered with capital investment.

Table 8: Income statement 2027-2032

	2027	2028	2029	2030	2031	2032
Sales Revenue	€ 1.010.130	€ 2.967.760	€ 7.999.762	€ 15.182.472	€ 30.718.414	€ 51.580.045
Other Revenue	€ 500.000	€ 500.000	€ 500.000	€ 500.000	€ 500.000	€ 500.000
Gross Revenue	€ 1.510.130	€ 3.467.760	€ 8.499.762	€ 15.682.472	€ 31.218.414	€ 52.080.045
COGS	256.080	268.560	136.240	146.120	146.120	156.000
Gross Margin	1.254.050	3.199.200	8.363.522	15.536.352	31.072.294	51.924.045
Full time equivalents	34	38	56	63	85	93
Personnel	€ 1.883.180	€ 2.121.080	€ 3.202.420	€ 3.556.020	€ 4.582.630	€ 4.905.030
Business development	€ 941.330	€ 1.009.580	€ 1.559.220	€ 1.668.420	€ 2.308.930	€ 2.308.930
Marketing & Communication	€ 78.000	€ 146.250	€ 302.900	€ 341.900	€ 392.600	€ 392.600
Technical team	€ 530.400	€ 631.800	€ 876.200	€ 1.081.600	€ 1.315.600	€ 1.638.000
Legal, HR & Admin	€ 146.250	€ 146.250	€ 214.500	€ 214.500	€ 253.500	€ 253.500
Management	€ 187.200	€ 187.200	€ 249.600	€ 249.600	€ 312.000	€ 312.000
Operating Expenses	€ 2.864.178	€ 3.926.258	€ 9.190.837	€ 12.910.068	€ 17.338.332	€ 25.198.710
Costs of sales (distributors)	€ 505.065	€ 1.483.880	€ 3.510.111	€ 6.658.262	€ 10.555.306	€ 17.788.554
Marketing	€ 1.700.000	€ 1.700.000	€ 4.720.000	€ 5.185.000	€ 5.866.500	€ 6.429.150
Housing	€ 163.200	€ 182.400	€ 268.800	€ 302.400	€ 408.000	€ 446.400
Services and outsourcing	€ 160.200	€ 161.400	€ 166.800	€ 168.900	€ 175.500	€ 177.900
Other	€ 335.713	€ 398.578	€ 525.126	€ 595.506	€ 333.026	€ 356.706
Total Expenses	€ 4.747.358	€ 6.047.338	€ 12.393.257	€ 16.466.088	€ 21.920.962	€ 30.103.740
EBIT	€ (3.493.308)	€ (2.848.138)	€ (4.029.735)	€ (929.736)	€ 9.151.332	€ 21.820.305

Part 2 – EIC Specific Information

9. IMPLEMENTATION PLAN

WORK PLAN AND RESOURCES

The initial steps of the project involve developing, refining, and consolidating all the technological components of the solutions. This work is divided into four main blocks: WP1 for Intervention and Monitoring Solutions, WP2 Feedback gathering and Refinement, WP3 for AI Models for Personalization, Diagnosis, and Prognosis and WP4 Integration and Testing. In WP1 and WP2, we will enhance the existing solutions, namely RGSclinic, RGSapp, and RGSwear, to maximize clinical outcomes, increase applicability in terms of patient profiles, and facilitate commercial scaling. Regarding RGSclinic, we will develop our proprietary monocular 3D body tracking to replace the currently used infrared camera (Microsoft Kinect Azure). This will make RGSclinic more scalable, affordable, and open the door for a home-based version of the product. For RGSapp, we will collaborate with a manufacturer to produce assistive devices, such as phone holders, that will enable patients with severe hemiparesis to use the application, as well as integrate grip force measurement and haptic feedback into the solution. Additionally, we will develop and integrate a hand tracking model into RGSapp to gather better diagnostic data. As for RGSwear, we will transition from a smartwatch app to custom-made bracelets, including only the necessary circuitry, to improve battery endurance and reduce costs. In WP3 and WP4, we will train and refine the existing algorithms for adaptive training, diagnosis, and prognosis. Specifically, we will develop tasks for diagnostic purposes, including a battery of tests in the motor and cognitive domains. These tests will allow us to provide daily objective assessments of the patient's condition, equivalent to traditional clinical scales. Additionally, we will develop new models to predict the specific training characteristics (e.g., frequency, intensity, volume) required for each patient to achieve and maintain maximum recovery potential. This will enable the creation of a virtual coach that guides patients after discharge, targeting the underserved segment of middle-low and low-income patients who cannot afford private treatment. The second stage of the project involves testing and validating the technology. The validation will be conducted in WP5 and will be divided into two phases. Firstly, a pilot study will be conducted using early versions of the solutions to refine the technology, logistics, and mitigate risks. Secondly, a clinical trial will be conducted, involving a randomized control trial to measure the clinical impact of the solution. During this stage, we will also ramp up communication and exploitation activities in WP6 and WP7, such as increasing participation in medical fairs and congresses, delivering workshops and webinars, and refining the Business Plan in preparation for the go-to-market phase in WP10 and WP11. The third stage of the project will focus on the market launch, which comprises four key tasks. Firstly, thorough testing and quality assurance measures will be implemented to produce the documentation required for certifications (ie, CE mark, FDA). Secondly, we will implement the marketing and communication strategy previously planned to create awareness and generate interest in our products to reach a wide audience. The third task involves establishing strategic partnerships and developing distribution channels. We will identify and engage potential collaborators such as healthcare providers, KOLs, rehabilitation centers, and medical equipment distributors. Furthermore, we will develop pricing strategies, sales incentives, and after-sales support to actively manage distributors and maximize market penetration and customer satisfaction. Finally, the launch and promotion of our solutions will be a focal point. We will organize a launch event to introduce our offerings to key stakeholders, leverage marketing channels such as medical fairs and congresses, conduct workshops and training sessions for healthcare professionals and potential users, and gather continuous feedback to refine our solutions and address any emerging concerns.

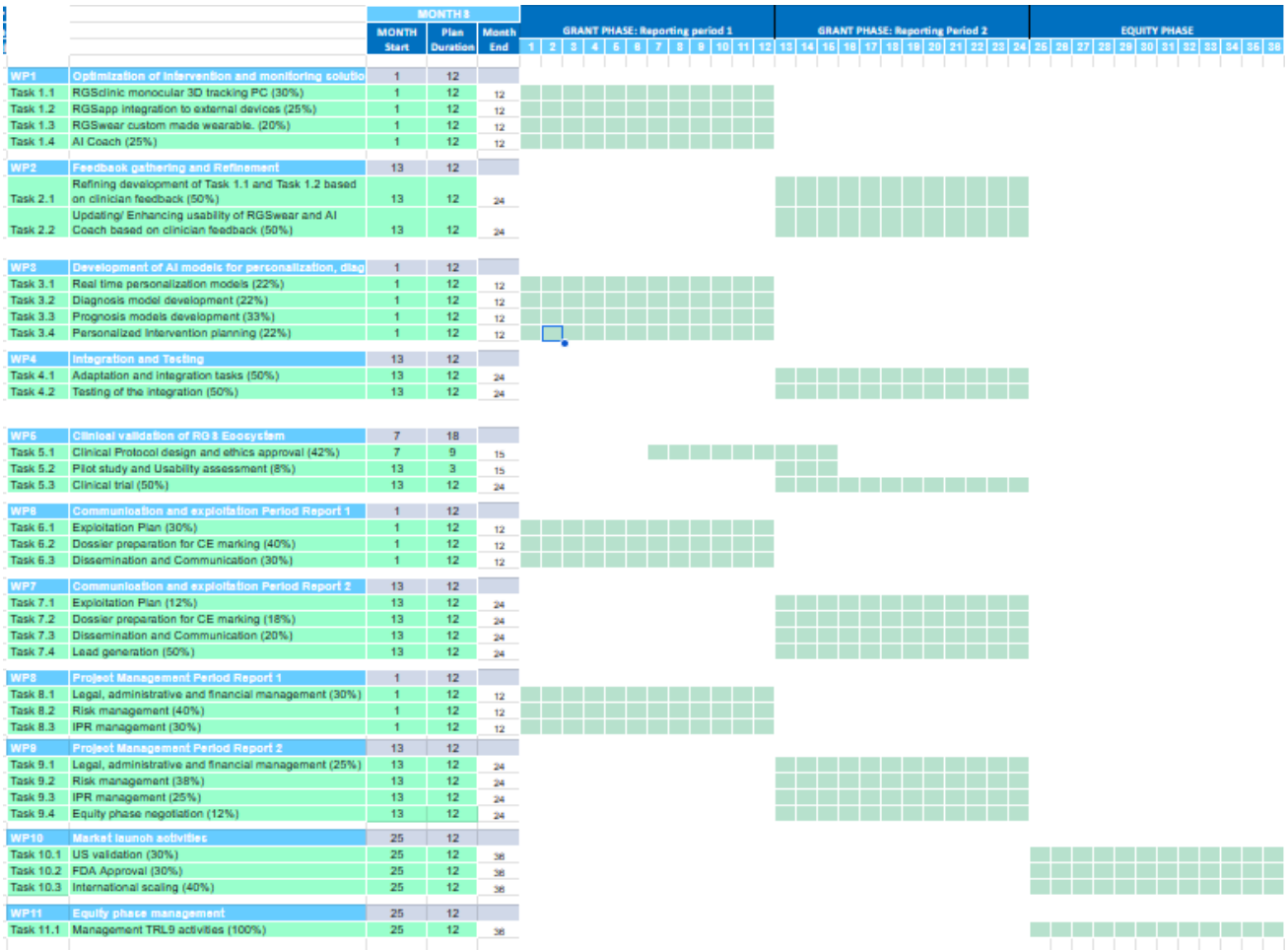

Figure 10: RGS Ecosystem project Gantt

Table 9: Work Packages of the grant component

WP	Type of WP	WP title	Objectives of the WP	Lead participant	PM	Start Month	End Month	Targetd TRL
1	technological development	Intervention and monitoring solutions	Development and refinement of the intervention and monitoring solutions	EOD	130	1	12	8
2	technological development	Feedback gathering and Refinement		EOD	72	13	24	8
3	technological development	AI models for personalization, diagnosis, and prognosis	Development and training of the AI patient models	EOD	60	1	12	8
4	technological development	Integration and Testing		EOD	24	13	24	8
5	technological development	Clinical validation	Validation of the technology to assess efficacy and impact in real world context	EOD	36	7	24	8

6	preparation to market activities	Communication and exploitation Period Report 1	Disseminate project results and pave the way for the market launch	EOD	80	1	12	8
7	preparation to market activities	Communication and exploitation Period Report 2	Disseminate project results and pave the way for the market launch	EOD	124	13	24	8
8	project management	Project Management Period Report 1	Ensure the project is executed according to plan	EOD	27	1	12	8
9	project management	Project Management Period Report 2	Ensure the project is executed according to plan	EOD	20	13	24	8

Table 10: Work Packages of the investment component

WP number	Type of WP	WP title	Objectives of the WP	Lead paricipant	Start Month	End Month	Targetd TRL
10	preparation to market activities	Market launch activities	The launch and scale the commercial activities	EOD	25	36	9
11	project management	Equity phase management	Management of TRL9 activities	EOD	25	36	9

Table 11: Work Packages descriptions

Work package number	**1**
Work package title	**Optimization of intervention and monitoring solutions for RGS Ecosystem**

Objectives

- To develop and integrate the intervention and monitoring components of the RGS Ecosystem
- To develop technology that can help reduce costs and improve interaction.

Task1.1 RGSclinic monocular 3D tracking PC (30%)

We will develop a monocular 3D tracking solution to replace the Microsoft Kinect Azure Camera, an infrared sensor currently used in RGSclinic to track the patient's movements. Our goal is to replace the Kinect Camera with a standard webcam using our proprietary algorithms, which will significantly reduce costs and facilitate scaling. The implementation will be made by relying on a 2D tracking system and developing a deep learning model trained from data gathered in a mocap studio to go from 2D to 3D pose estimation. Developing our own tracking algorithms will allow us to have better performance in the training tasks and most importantly, it will allow us to prescind from external hardware, reducing significantly product costs and improving scalability.

Task1.2 RGSapp integration to external devices (25%)

RGSapp will be integrated to external physical devices to help patients with severe hemiparesis work with antigravity solutions for the upper limbs to include pressure sensing, stimulation, and haptic feedback in the hand and upper limb traying activities. For this, we will integrate RGSapp with interactive sensors via cable and Bluetooth and will work with Hankamp Rehab for the development of ergonomic anti-gravity devices. This integration will allow us to significantly expand the population of stroke patients that can

benefit from the solution to include severe hemiparesis patients that cannot perform exercises against gravity and even hemiplegic patients that can be stimulated with the solution.
Subcontractor: Hankamp

Task1.3 RGSwear custom made wearable. (20%)

We will work with a provider of wearable electronics to develop a version of the solution that does not require a smartwatch. We will integrate a microchip board, induction charger, a gyroscope, and accelerometer to collect and process that data on arm use during the activities of the daily living (ADLs) Producing our own hardware will allow us to significantly reduce the costs of user while improving value by significantly improving the precision and quality of the data and extending the battery life.
Subcontractor: Wearables provider

Task1.4 AI Coach (25%)

Development of a virtual coach to increase engagement and adherence to treatment. The coach will collect the data from the RGS database including training frequency, adherence, performance and spontaneous arm use. This data will be processed by the AI module running in Eodyne's backend to customize messages for each user, which will be managed by a Firebase module. Within the application front end written in C#/Unity, the coach will help users navigate the solution, provide instructions and feedback and motivational messages. The AI coach will improve user experience to ultimately increase adherence, one of the biggest challenges in neurorehabilitation, and will pave the way to empowering B2C customers.

Work package number	**2**
Work package title	**Feedback gathering and Refinement**

Objectives

- To refine the intervention and monitoring components of the RGS Ecosystem
- To maximize user experience to facilitate the adoption of the end user solutions

Task2.1 Refining development of Task 1.1 and Task 1.2 based on clinician feedback (50%)

Integrating the newly developed 3D monocular tracking solution with the RGS ecosystem and conducting comprehensive assessments of its functionality and efficacy. This process will occur in two phases of testing.

The first phase involves in-house testing, during which developers and testers will assess the usability of the technology to ensure it is bug-free and user-friendly. In the second phase, clinicians feedback will be crucial in refining the solution.

Similar steps will be taken for advancing the integration of RGSapp with external devices. Subsequently, clinician feedback will be collected to align the technology with the needs of stakeholders.

Task2.2 Usability Enhancement of RGSwear and AI Coach through clinician feedback (50%)

Building upon the development of RGSwear (Task 1.3) and the AI Coach (Task 1.4), this task focuses on refining user experience and functionality based on input from healthcare professionals specializing in stroke rehabilitation.

Clinician feedback will be solicited to identify areas for improvement in RGSwear, ensuring that the custom-made wearable provides accurate and insightful data on arm use during activities of daily living (ADLs). Additionally, suggestions for enhancing user comfort, ease of use, and battery life will be considered to optimize the overall usability of RGSwear.

Similarly, feedback will be collected on the AI Coach to fine-tune its functionality in providing personalized guidance, feedback, and motivational messages to users. Clinician input will help tailor the AI Coach to better meet the needs and preferences of both healthcare professionals and patients, ultimately enhancing engagement and adherence to treatment.

Work package number	**3**
Work package title	**Development of AI models for personalization, diagnosis, and prognosis**

Objectives

The objective of this WP is to develop, train, and validate patients models to: personalize training in real time, generate objective clinical assessments, predict recovery path, and tailor training programs to maximize outcomes for patients. We will work in collaboration with the company SaddlePoint Science.

Task3.1 Real time personalization models (22%)

The RGS training activities consist of specific tasks to be completed in VR/AR scenarios. The activity settings, which determine the task's difficulty, are controlled by the so-called difficulty modulators, which we denote by a vector m = (m1, . . . mM), where M is the number of modulators of the task in hand. WE will determine the way the performance is affected by the difficulty modulators in a personalized way, which we refer to as estimation of the patient's complexity surface to then propose new values of difficulty modulators during the activity, in a way to explore the complex surface and keep the activity variable and engaging, which we refer to as sampling of the complex surface.
The real- time personalization will have double effect, first, it will make the training activities more engaging and variable, and second, it will modulate complexity to maximize the clinical outcomes for patients.
Subcontractor: SaddlePoint

Task3.2 Diagnosis model development and integration (22%)

The devices in the RGS Ecosystem generate vast amounts of data for each patient in the form of JSON files that contain the recorded position of every tracked body parts (e.g., head, trunk, shoulder, elbow, and wrist joints in the case of RGSclinic) and training events and internal parameters of the game (e.g., hits and errors, difficulty level). The task of the diagnosis stage is therefore firstly to extract, from this large amount of data, a few clinically relevant parameters. Practically, for each activity, we will evaluate the relevant parameters that are then stored in a devoted SQL database together with the patient id, game id, session id, and datetime. Finally, we convert them into clinical scales and information that can be easily shared with clinicians and patients.
The diagnosis models will be an extremely useful tool for therapists to get regular and objective assessments of the patient's condition even remotely. Therefore, they will be able to frequently monitor the recovery dynamics of patients and save considerable time otherwise needed to conduct lengthy subjective assessment in person.
Subcontractor: Saddle Point

Task3.3 Prognosis models development and integration (33%)

We will implement a Longitudinal Linear Mixture Model (LLMM) as an adaptation of van der Vliet model, to parametrize the probabilities for a population of patients to exhibit specific values for their measured arm use functionality after stroke, as measured on some clinical scale (typically Fugl-Meyer). The advantage of using this specific model is that we can rely on the training performed in the literature on a vast legacy dataset of stroke recovery. Using Monte-Carlo sampling to simultaneously calculate the number of subgroups in the data and the model parameters, van der Vliet et al, we can identify subgroups in the recovery path. The LLMM allows to provide predictions on the future clinical status of the patient based on current therapy. The main outcome of the LLMM is the prediction of the patient's pathway to recovery for the first 6 months after the stroke.
This will be one of the most innovative components of the RGS Ecosystem, as it will the first interpretable AI algorithm for stroke prognosis that we know of in the market. This solution will not only help professional predict patient recovery, but algo question, interpret and improve the results of the algorithms.
Subcontractor: SaddlePoint

Task3.4 Personalized Intervention planning (22%)

By using the prognostic model developed and implemented in WP2 (T2.3) in `reverse engineering' mode (after inference of patient-specific model parameters from data), it can be used for clinical decision support, by identifying (i) the level of individual function improvement achievable, (ii) optimal individual treatment in terms of personalized revalidation training protocols and regimens, and (iii) estimates of corresponding therapy benefits in terms of motor and cognitive function. This clinical support tool will be coded and integrated within the clinical user interface.
This will be one of the main clinical decision support tools that will help therapists decide what is the best training program for each patient in order to achieve their full recovery potential. Technologically, it will close the data loop, as the data generated during the training sessions will be used to generate prognosis assessments that will in turn predict the best possible training program, which will finally be used to modulate the parameters of the training session.
Subcontractor: SaddlePoint

Work package number	4

Work package title	Integration and Testing

Objectives

The objective of this WP is to achieve seamless integration, adaptation, and thorough testing of the various models and tools developed in previous tasks within the RGS-E solutions. We will work in collaboration with the company SaddlePoint Science.

Task4.1 Adaptation and integration tasks **(50%)**

Task 4.1 focuses on the seamless integration and adaptation of the various models developed in previous tasks (Tasks 3.1, 3.2, 3.3, and 3.4) within the RGS Ecosystem. This task aims to ensure that the functionalities of these models complement each other and contribute synergistically to the goal of enhancing stroke rehabilitation outcomes. This framework will facilitate data-driven decision-making, personalized treatment planning, and continuous monitoring of patient progress.

Subcontractor: SaddlePoint

Task4.2 Testing of the integration **(50%)**

The testing process will involve multiple stages, including functional testing, performance testing, and user acceptance testing. Functional testing will assess the functionality of each component within the integrated system, ensuring that all features work as intended and meet the specified requirements. Performance testing will evaluate the system's responsiveness, scalability, and reliability under various load conditions, ensuring that it can handle the demands of clinical use effectively.

User acceptance testing will involve engaging clinicians and healthcare professionals to evaluate the usability, intuitiveness, and overall satisfaction with the integrated system. Feedback from clincians will be collected to identify any usability issues.

Subcontractor: SaddlePoint

Work package number	5
Work package title	Clinical validation of RGS Ecosystem

Objectives

- Design and carry out the validation of RGS through focus groups, pilot studies and a clinical trial.
- Collect feedback from clinicians and patients and assess the usability of the solution.

Task5.1 Clinical Protocol design and ethics approval (42%)

Design the clinical trial protocol and prepare the documentation for the approval by the ethics committee and national regulatory agencies of medical devices of each of the clinical partners, following the EU regulations and specific regulations of each country and hospital, including trial registration. Coordination of trial rollout and organizational procedures (recruitment process, deployment process, support processes, etc.). Identification of trial risks and establishment of mitigation plans.

The clinical protocol design will maximize the value of the results of the validation and ensure that EU regulations and guidelines are closely followed.

Subcontractor: Clinical partner (Hospital)

Task5.2 Pilot study and Usability assessment (8%)

We will make a first implementation of the technology in the testing site to gather first insights into using the platform and fine tune logistics, processes and technology. We will establish focus groups with clinicians, caregivers, patients, and/or patient associations. Evaluate their expectations, goals, fears, and social identification (sex and gender aspects, age, and other specific determinants) to support the development and the clinical trial. Benefits/risk assessment of potential adverse events, side effects, expected treatment compliance, and adherence. Perform pilot studies where the clinical partners.

The pilot study reduces risks in the clinical validation by testing the entire deployment process and the interaction with the technology by all stakeholders.

Subcontractor: Clinical partner (Hospital)

Task5.3 Clinical trial (50%)

We will subcontract a CRO and hospital to conduct a randomized controlled trial including at least 30 patients. Patients are randomized into two groups: intervention group (RGS) and control group (treatment as usual), with an allocation ratio of 3:1. Stroke patients are recruited amongst the outpatients of each clinic participating in the project. Patients in the intervention group train with RGS according to the clinicians' prescription and before or after their training session. The control group receives only treatment as usual. Treatment must be at least 30 minutes per session. The RGS group will stop when the patient requests so, or the therapist thinks it is not relevant anymore.

The results of the clinical validation will be crucial to demonstrate the clinical value of the solutions to customers. Subcontractor: CRO

Work package number	6
Work package title	**Communication and exploitation Period Report 1**
Objectives - Analyze the market to validate and improve value propositions and business models - Develop a business plan commercialization strategy for the European and global markets. - Generate visibility by doing marketing activities and participating in events - Reach out to potential customers and get early adopters	
Task6.1 Exploitation Plan (30%) We will begin by conducting market research to gain further understanding our market. We will identify the target audience, competitors, trends, and potential opportunities. Based on the market research, we will define a unique value proposition for the RGS Ecosystem. Based on this, we will develop a business model that outlines the revenue generation channels and a commercialization strategy to reach our target audience. We will identify key opinion leaders in the stroke field and establish relationships with them to promote our products and tools. In order to do this, we will develop a detailed execution plan that outlines the step-by-step actions required to bring the RGS Ecosystem to market. We will include timelines, milestones, and responsibilities for each phase of the plan, which will be continuously monitored and adjusted based on market feedback and emerging trends. **Task6.2 Dossier preparation for CE marking (40%)** Based on the EU Medical Devices Regulation (MDR) we will compile the required technical documentation including design specifications, product descriptions, development processes, component information, and details of any software or firmware used. We will perform a thorough risk assessment for the RGS Ecosystem and develop risk control measures. We will collect and analyze the clinical data to demonstrate the safety and clinical benefit of the RGS Ecosystem. Additionally, we will create a post-market surveillance plan that outlines we will monitor the performance and safety of our products after they are placed on the market. This plan will describe the processes for gathering post-market data, analyzing adverse events, and implementing corrective actions if necessary. We will draft a Declaration of Conformity (DoC) stating the compliance with the applicable EU regulations. Finally, we will submit the complete dossier to a Notified Body. **Task6.3 Dissemination and Communication (30%)** We will begin by identifying the key stakeholders and target audiences for the project including healthcare professionals, hospitals, stroke centers, patients and their families, medical associations, researchers, and policy makers. We will define the objectives of the communication plan, such as raising awareness about the tools, promoting their benefits, and encouraging adoption in clinical practice. To achieve this, we will craft clear and concise key messages that highlight the unique features, benefits, and potential impact of the intervention, diagnosis, and prognosis tools. The next step is to choose the most appropriate communication channels to reach each target audience effectively such as scientific publications, medical conferences, websites, social media platforms, press releases, and patient support groups. Finally, we will create the content and materials, this can include brochures, videos, testimonials, case studies, and scientific articles.	

Work package number	7
Work package title	**Communication and exploitation Report Period 2**
Objectives - Same as previous WP	
Task7.1 Exploitation Plan (12%) Same as Task 6.1 for the Report Period 2 (M13-M24) **Task7.2 Dossier preparation for CE marking (18%)** Same as Task 6.2 for the Report Period 2 (M13-M24) **Task7.3 Dissemination and Communication (20%)** Same as Task 6.3 for the Report Period 2 (M13-M24)	

Task7.4 Lead generation (50%)
We will use targeted online advertising campaigns to reach healthcare professionals, hospitals, stroke centers, and relevant organizations. Platforms such as Google Ads, social media platforms, and industry-specific websites can be effective in reaching the desired audience. We will develop high-quality content, such as blog posts, whitepapers, and case studies, that address the challenges and solutions related to stroke intervention, diagnosis, and prognosis. Additionally, we will deliver webinars and educational events targeting healthcare professionals and organizations involved in stroke care. Moreover, we will seek partnerships with relevant organizations, medical associations, or industry influencers who have established networks in the stroke care field. We will also attend Trade shows and conferences on stroke care. Finally, we will develop an email marketing strategy to regularly communicate with leads and provide updates, educational content, success stories, and new features related to the RGS Ecosystem tools.

Work package number	8
Work package title	Project Management Period Report 1

Objectives
Manage the project's development until reaching the commercial stage and ensure that work-package timelines and deliverables are conducted in line with the work plan and allocated budget to fulfil the established scientific, technological, and commercial milestones and objectives.

Task8.1 Legal, administrative and financial management (30%)
Management of the project budget and resources according to the pre-established financial agreement. Progress Reports shall be issued according to the timing and rules established under the Grant Agreement. Assurance of the effective progress of the technical activities in the project in terms of time, budget and scope, and monitor regulatory framework. Establishing good legal, financial and administrative management will ensure the successful completion of the project.
Task8.2 Risk management 40%)
Pursue the objective of identifying risks and drawing up plans to minimize their effect on the project. Supervise the periodic risk analysis, resolving issues and conflicts. Per will be responsible for the timely and effective execution of the WP work, and for suggesting any potential work re-planning and implementation of corrective actions.
Task8.3 IPR management (30%)
Ensure the intellectual protection of Eodyne's technology and its components, which will be done according to the following activities: i) patent prosecution to reach the milestone of granted patents in EU and USA, ii) perform a technology watch over our patented technology If considered necessary, we will also redact documents and filing applications of new patents or any other tool for intellectual protection; (iii) Registration of trademarks in EU, USA, and other markets.

Work package number	9
Work package title	Project Management Report Period 2

Objectives
Same as WP8.

Task9.1 Legal, administrative and financial management (25%)
Same as Task 8.1 for the Period Report 2 (M13-M24)
Task9.2 Risk management (38%)
Same as Task 8.2 for the Period Report 2 (M13-M24)
Task9.3 IPR management (25%)
Same as Task 8.3 for the Report Period 2 (M13-M24)
Task9.4 Equity phase negotiation (12%)
We will secure EIC Grant Accelerator post-project financing. We will engage with the EIC Fund and private co-investors to reach final commercialization stage. This task is connected to our cost's estimations for the expected expansion of the RGS Ecosystem in the target countries.

As part of this task, we will be committed to perform financial and commercial due diligence process to reach an agreement with the potential co-investor(s) by the Investment Advisor, the Investment Committee and the relevant EIC service providers. This task will prepare our company and large network of collaborators will help to attract investors, secure funding and be ready for the negotiation and due diligence for TRL 9 project activities equity and above.

Work package number	10
Work package title	**Market launch activities**
Objectives Bring The RGS Ecosystem to the global market and build an organization that can support and grow the business in all aspects. The equity investment will be mainly focused on market deployment tasks and future actions to afford customer's demand.	
Task10.1 US validation (30%) Involves establishing partnerships and conducting clinical trials or studies within the United States to gather evidence and validate the effectiveness and safety of the RGS Ecosystem with stroke patients. This may involve collaborating with medical institutions, recruiting participants, collecting and analyzing data, and ensuring that the solution meets the required standards and regulations. Generating clinical evidence in the US will allow us to obtain the require certifications and will ease the adoption of US customers since it will demonstrate the effectivity of the solution in the context of local practice standards. Subcontractor: US Hospital **Task10.2 FDA Approval (30%)** This task involves compiling all the necessary documentation, including clinical trial data, technical specifications, manufacturing processes, and safety information, to submit a comprehensive application to the FDA. It may also involve responding to inquiries and providing additional information requested by the FDA during the review process. The goal is to receive FDA clearance or approval, which will allow the RGS Ecosystem to be legally marketed and sold in the United States. Obtaining approval from FDA is a crucial step in the commercialization of a medical device like the RGS Ecosystem **Task10.3 International scaling (40%)** We will establish distribution channels and partnerships in each target market and develop comprehensive marketing and brand awareness campaigns tailored to each market. Leverage various channels such as digital marketing, industry events, conferences, and medical symposiums to reach our target audience. We will start sales in Spain and the Benelux, where we already have partnerships and early adopters. Based on the first market experiences, we will expand operations into Germany, adapting the solution, marketing messages, and distribution strategies to meet the specific requirements and preferences of the German healthcare market. Simultaneously, and as we process the FDA approval we will develop a market entry strategy for the US, including identifying potential distributors or strategic partners, building relationships with key stakeholders, and planning targeted marketing campaigns to create awareness and generate demand. Opening new markets will help us reach sales traction to attract capital and boos company growth.	

Work package number	11
Work package title	**Equity phase management**
Objectives Manage all the TRL 9 activities involved in market launch and scaling.	
Task11.1 Management TRL9 activities (100%) This task englobes the coordination, planning, and management of the activities necessary to organize and control the commercialization plan of the project in preparation for market launch. This includes monitoring the budget and resources allocated to TRL9 activities. This also includes strengthening our retention plan to ensure that we maintain the core knowledge and skills specific to RGS Ecosystem provided by our employees and exploring new funding routes to further develop Eodyne's portfolio.	

Table 12: List of deliverables

Deliverable number	Deliverable name	Short description	WP	Type	Dissemination level	Delivery date
8.1	Data Management Plan	Data Management Plan	8	DMP	SEN	6
6.1	Plan for dissemination and exploitation	Dissemination and exploitation plan	6	R	SEN	6
8.2	Intermediate Project Report	A concise document detailing the project's progress over year 1, capturing milestones achieved, challenges faced, financial status, and any deviations from the initial plan.	8	R	SEN	12
1.1	First version of intervention solutions (Clinical Prototype)	Integrated prototype versions of RGSclinic, RGSapp, and RGSwear	1	DEM	SEN	12
3.1	First version of patient models (Clinical Prototype)	First version of diagnosis and prognosis models calibrated with legacy data	3	DEM	SEN	12
6.1	Business plan (initial version)	Business plan	6	DEM	SEN	12
5.1	Clinical protocol (Draft)	Initial version of clinical protocol elaborated with clinical partner	5	R	SEN	13
5.2	Clinical protocol	Clinical protocol approved by ethics committee	5	DEM	SEN	14
2.1	Commercial version of intervention solutions	Commercial versions of RGSclinic, RGSapp, and RGSwear ready for commercialization	2	DEM	SEN	24
4.2	Commercial version of patient models	Commercial versions of diagnosis and prognosis models ready for commercialization	4	DEM	SEN	24
5.3	Clinical validation report	Clinical validation report	5	DEM	SEN	24
7.1	Business plan (Final version)	Final version of Business plan	7	DEM	SEN	24
7.2	Dossier for CE marking	Dossier for CE marking is ready	7	DEM	SEN	24
9.1	Equity readiness report	Document summarizing the company’s economics, including a discussion of the key drivers of revenues and expenses, target price, investment thesis, valuation, and risks	9	R	SEN	24
7.3	Communication and Dissemination final report	Information on the channels and methods used for C&D and their outcomes and impact.	7	R	SEN	24

9.2	Final Project Report	A concise document detailing the project's outcome capturing milestones achieved, challenges faced, financial status, and any deviations from the initial plan.	9	R	SEN	24

Table 13: List of milestones

Milestone number	Milestone name	WP	Due date	Means of verification
1	Completion of advanced prototype of RGS Ecosystem	1	M12	• Developing alternative to Kinect Azure. • Integration of RGS Ecosystem with external devices. • Prototype of AI Coach for enhanced user engagement.
2	Prototype of personalization model ready	3	M12	• Completion of the initial development phase for real-time personalization models. • Successful extraction of clinically relevant parameters from the vast amount of data generated by RGS devices.
3	Pilot study has started	5	M13	• Documentation of pilot study initiation including signed agreements with participating sites. • Confirmation of recruitment of participants for the pilot study. • Commencement of data collection and intervention implementation as per the study protocol.
4	Eodyne is Equity ready	9	M18	• Valuation Assessment: Determine the company's worth. • Investor Presentation: Prepare a comprehensive pitch for investors. • Due Diligence Documentation: Compile necessary documents for investors.
5	Clinical trial is finished	5	M24	• Completion of data collection for the clinical trial. • Review and approval of study results by the appropriate regulatory bodies. • Finalization of trial report including statistical analysis and outcomes.
6	The RGS intervention and monitoring solutions are ready and integrated	2	M24	• Demonstration of the fully developed and integrated intervention and monitoring solutions. • Testing and validation of the integrated solutions against predefined criteria and performance metrics. • Feedback and approval from stakeholders on the functionality and usability of the solutions.
7	The diagnosis and prognosis models have been trained and validated	4	M24	• Evaluation of the accuracy and reliability of the trained models through validation datasets. • Comparison of model predictions against gold standard diagnostic criteria or expert opinions. • Documentation of model training processes, parameter settings, and validation results.
8	Leads have been established	7	M24	• Identification and documentation of established leads or potential customers. • Communication records indicating interest or intent for collaboration or adoption. • Agreements or contracts signed with interested parties for further engagement.
9	First early adopters	10	M30	• Confirmation of initial users or organizations adopting the technology.

				• Feedback and testimonials from early adopters regarding the effectiveness and usability of the solutions. • Monitoring of usage and implementation metrics to assess adoption rates and user satisfaction.
10	Distributor in Europe signed	10	M33	• Signed distribution agreement with a distributor in Europe. • Legal documentation confirming the partnership and distribution rights. • Communication records indicating the commencement of distribution activities in Europe.
11	FDA dossier submitted	10	M36	• Submission of a complete and accurate FDA dossier for regulatory approval. • Confirmation of dossier receipt and initial review by the FDA. • Communication with regulatory authorities regarding any additional information or clarifications required

Table 14: List of risk related to the project implementation.

Description of risk (LIKELYHOOD/SEVERITY)	WP	Proposed risk-mitigation measures
LOW PREDICTING POWER (MEDIUM/HIGH): The most innovative aspect of this project is the implementation of interpretable AI algorithms that can accurately predict the patient recovery potential and path. Stroke symptomatology is very diverse and disease-independent factors (eg, economic, social, personal) may play a key role in recovery. The main risk is that the predictive power is not sufficient to be a useful tool in daily practice.	3,4	Two main mitigation measures can be applied. First, more subjects can be included in subsequent clinical studies to collect more data and increase the statistical significance of the findings. Second, disease-independent variables, such as social background, can be incorporated into the patient models used in the trial. Stroke recovery is influenced by various factors beyond the pathology itself, including social determinants, environmental factors, and individual characteristics. By factoring in these variables, the models can account for the additional causal forces that play a role in the recovery path of patients.
LOW PATIENT RECRUITMENT (MEDIUM/MEDIUM): Several factors might difficult patient recruitment or increase dropouts. For example, the eligibility criteria may limit the pool of eligible participants, patients may not be aware or understand the potential benefits of the solution, the trial procedures and commitment might become inconvenient for participants, or patients could already be recruited for other competing ongoing clinical trials.	5	Several measures can be implemented to mitigate this risk, such as 1) Collaborating with multiple clinical sites to access a larger pool of potential participants. 2) Engaging with stroke support organizations to help raise awareness about the clinical trial. 3) Offering incentives and compensation to encourage enrolment and offset any inconvenience associated with participation. 4) Streamlining screening process to identify eligible participants quickly, reducing the time and effort required for recruitment.
DELAYS OR FAILURE WITH REGULATORY OR ETHICAL COMPLIANCE FOR CLINICAL TRIALS (LOW/HIGH)	5	To mitigate potential regulatory and ethical compliance issues, we have established a comprehensive that includes setting clear timelines for regulatory submissions, seeking necessary approvals in advance, and ensuring meticulous documentation. Throughout the trial, we will adhere to regulatory and ethical requirements while maintaining close communication with ethics committees and regulatory bodies to promptly address any concerns or queries. These measures are designed to reduce the likelihood of delays or failure in compliance due to the high severity of this risk.

CRITICAL DELIVERABLES ARE DELAYED (LOW/MEDIUM)	1-9	Measures and procedures to regularly monitor the work are specified in the project management plan; so appropriate mitigation plans can be devised for each case. The PM and the involved Teams will be responsible for these plans. Our previous experience in European project management will reduce this risk and its possible impact.

Table 15: Subcontracting costs

Subcontracting	Cost (€)	Description of tasks and justification of the best value for money principle
Phone stand development	83.400	Development of phone stand (WP1) Subcontractor: Hankamp Rehab is a leading company in the development, production and distribution of innovative rehabilitation and assistive technology. Hankamp Rehab has a large (international) network of suppliers, distributors, end-users, research partners, and a deep understanding of the market. Hankamp Rehab has experienced staff members with a background in Biomedical Engineering, Robotics, Mechanical Engineering, and Human Movement Sciences.
Full upper limb rehabilitation system	80.000	Development of full upper limb rehabilitation system (WP2). Subcontractor: Hankamp
AI Models	79.000	Development of AI models for personalization, diagnosis, and prognosis (WP3). Subcontractor: Saddle Point Saddle Point Science Europe is a company with deep knowledge and expertise in the development of advanced data analysis and explainable artificial intelligence methods for medical applications, which will be a core activity for this project and one of the main differentials of its products. Saddle Point focuses specifically on the data analytics challenges posed by modern data-driven personalized medicine
Prognosis models development and integration	75.000	Personalized intervention planning (WP4). Subcontractor Saddle Point
CRO services	25.000	CRO advise and execution (WP 5). Subcontracting based on best offer selection
Clinical validation	59.000	Clinical trial (WP 5). Subcontracting based on best offer selection
TOTAL	401.400	

Table 16: Purchase costs

Purchase costs	Cost (€)	Justification
Travel and subsistence	35.000	For work meetings with subcontractors and service providers. Assistance with events related to the project and visits
Equipment	43.300	8 RGS system stations for rehabilitation centers. and 30 mobile devices (phones, smart watches, tablets)
Other goods, works and services	80.000	Mocap study 10.000 euros (WP1), Market study 10.000 euros (WP 6), Events 10.000 euros (WP6), Advise on CE 15.000 euros (WP6) Market study 10.000 euros (WP7), Events 10.000 euros (WP7), Legal service IP 5.000 euros (WP8), Legal adviser in IP strategy designer 10.000 euros (WP 9)
TOTAL	178.300	

10. HOW EU SUPPORT TAKES THE COMPANY TO THE NEXT VALUE POINT

HOW THE EIC FUNDING WILL BENEFIT THE SCALABILITY OF EODYNE

The project is characterized by its high ambition and high risk. To instill confidence and attract investment, we must achieve several key milestones, including demonstrating the predictive power of our prognosis algorithms and ensuring successful market adoption of our solutions by health professionals and patients. This is where **the support of the EIC becomes crucial**, as it will help us mitigate these risks and reach a TRL of 8-9. While we have explored other funding avenues such as national and regional programs like CDTI and ACCIO calls, we have found that their resources are insufficient to effectively deploy our solution in the market.

We estimate we will need a total of 15.8M€ (2.5M€ grant + 12.2M€ investment + 1.1M€ own resources) to cover the technological development needed and support the launch and scaling in the first four years of commercialization. The equity investment (of which half will be covered by private investment) will be divided in two stages, a Series A of 6.3M€ in the first year of commercial activity to launch sales, and a Series B round of 5.9M€ to scale commercially. This funding will support our market entry strategies and facilitate the refinement and enhancement of our innovative solutions. As a result, we will be better equipped to meet the evolving needs of our customers and solidify our position as a leading player in the telemedicine industry.

The funding provided by the EIC will enable us to achieve the objective TRL of 8-9 and overcome initial market entry barriers. By providing financial support for validation, certification, and regulatory costs the EIC funding will help to significantly reduce time to market. Furthermore, the EIC funding will help us fine-tune our business model, optimizing operational efficiency and financial sustainability. By reducing fixed costs and enhancing profit margins, we will be better positioned to generate significant returns on investment and attract further private investments. Moreover, by de-risking the project through the support of the EIC, we will significantly enhance our appeal to potential investors. The increased TRL will demonstrate the feasibility and potential of our solution, making it an attractive proposition for private investment. Overall, the EIC funding represents a strategic step that will enable our growth trajectory and pave the way for sustainable success.

EXIT STRATEGY

Our exit strategy is centred in a potential acquisition from a major player in the healthcare industry such as Medtronic, with whom we already collaborate (A LOI from Medtronic is included in the Annex). Medtronic's strategy is to cover the entire pipeline of rehabilitation, from admission to discharge and home-based training, which is aligned with Eodyne's mission and the project goals. By consistently demonstrating the value and impact of our RGS Ecosystem, we anticipate attracting the interest of industry leaders and creating a competitive environment for potential acquirers, maximizing the potential return on investment for our stakeholders.

Based on our projections, we estimate gross annual revenues over 52M€ within a six-year timeframe from the start of commercialization. Specially after COVID-19, valuations in the telemedicine sector have raised and are currently determined by revenue multiples of 5.5x. Based on these benchmarks, we anticipate that our projected revenue could lead to a valuation range between 286M€. **As such, investors stand to realize a substantial 11x return on their initial investment assuming a pre-money company valuation of 12M€.**

In summary, our growth projections and anticipated valuation demonstrate the growth potential of our innovation. With a strategic focus on securing a partnership or acquisition with a prominent healthcare industry player, we are well-positioned to realize our goals and deliver significant value to our investors, stakeholders, and the healthcare community at large.

11. THE EIC FUNDING REQUEST

We are currently seeking blended funding to support our project, combining both grant funding and equity investment. **In the initial grant phase, which spans the first two years of the project, we have allocated a budget of approximately 3.57M€.** This budget will be primarily utilized in Work Packages 1 to 9, focusing on technological development, clinical validation, and preparing for the commercial exploitation of the project's outcomes. Of the total grant budget, 70% will be covered by the grant funding and 30% will be covered with Eodyne's own resources.

Moving into the subsequent equity phase and the commercialization of the project's results, we will require a capital injection of approximately 12.2M€. This investment will be split in two stages, a Series A of 6.3M€ at the start of the commercialization phase to kick-off sales, and a 5.9M€ Series B in year three of commercialization to scale activities. By splitting investment in two stages, we will de-risk the project for private investors and significantly increase the valuation of the company to have a better equity deal in our B Series. Therefore, in total, we will request 6.1M€ of investment from the EIC.

Based on our projections and financial analysis, this investment will enable us to break-even third year of commercialization (2029). However, as explained, we will seek a capital injection on this year to accelerate the scale up, and hence the projections show a negative balance on this year, reflecting an increased expenditure in marketing and growth of the commercial teams. By achieving this milestone, we will have established a solid foundation for subsequent exponential growth. The investment will be strategically utilized to drive sales, expand into new markets, and solidify our position as a leading provider of telemedicine solutions in the neurorehabilitation space. Overall, **the blended funding approach we are pursuing allows us to leverage both grant support and equity investment, enabling us to effectively execute our commercialization plan while minimizing financial risk.** With the allocated budget, we are confident in our ability to achieve financial sustainability and drive continuous growth beyond the project timeline.

Table 17: Financing breakdown

INNOVATION ACTIVITIES (TRL6-TRL8)	MARKET/SCALE UP ACTIVITIES (TRL 9)
EIC ACCELERATOR (2024-2026)	MARKET LAUNCH IN 2027
3.57M€	1.2M€
FINANCING BREAKDOWN	
Amount of grant requested to EIC: 2.5M €	
Total Investment needed: 11.3€	
Investment requested to EIC: 6.1€	
Total funding from other sources: 6.1M€	

DISCUSSIONS WITH PRIVATE AND PUBLIC INVESTORS:

Currently, we in discussions with Nina Capital, a venture capital firm specializing in health tech companies. We have presented our RGS Ecosystem project to them, and they have shown a keen interest in investing once we reach TRL 8. In fact, **we have included a Letter of Intent (LoI) from Nina Capital in the annex, which serves as a testament to their commitment and the potential they see in our venture**. Additionally, we are talking with The East Netherlands Development Agency (OOST NL), which supports international entrepreneurs throughout the entire process of establishing businesses and fostering growth in the region. OOST NL has supported more than 1,000 companies from all over the world. **OOSTNL has expressed interest in co-investing up to 2M€ in Eodyne** for starting-up a Dutch branch in the region. A LOI from OOSTNL is included in the annex.

12. BROAD IMPACTS

SOCIETAL, ECONOMIC, ENVIRONMENTAL AND/OR CLIMATE IMPACT

The RGS Ecosystem has the potential for significant societal, economic, and environmental impacts.

SOCIETAL IMPACT: The RGS Ecosystem positively impacts society by improving the quality of life for stroke patients. By providing effective and accessible neurorehabilitation solutions, it helps patients regain their motor functions, enhance their independence, and reintegrate into society. This leads to improved overall well-being, increased confidence, and a higher level of participation in daily activities for individuals affected by stroke. Moreover, by helping patients regain independence, we can have a significant impact in the lives of informal caregivers, such as friends and relatives, that in 2017 provided 1.3 billion hours of care to stroke patients.

ECONOMIC IMPACT: The RGS Ecosystem can produce notable economic impact by reducing healthcare costs associated with stroke rehabilitation. Traditional rehabilitation methods often require extensive in-person sessions and specialized equipment, which can be costly. By leveraging technology and tele-rehabilitation, the RGS Ecosystem offers a cost-effective solution that can be accessed remotely, minimizing the need for frequent clinic visits. This reduces healthcare expenditures for both patients and healthcare systems, allowing resources to be allocated more efficiently. Additionally, by improving outcomes and retention, the overall economy will benefit from a higher rate of patients returning to work. Stroke-related morbidity accounted for 38 million working days lost, which accounted for €6.3 billion of costs in 2017.

ENVIRONMENTAL IMPACT: The RGS Ecosystem contributes to environmental sustainability by reducing the carbon footprint associated with traditional rehabilitation practices. By enabling tele-rehabilitation and leveraging consumer electronics like smartphones, the need for travel to rehabilitation centers is minimized. This leads to a decrease in transportation-related emissions and energy consumption, resulting in a smaller environmental impact. Additionally, Stroke survivors who can regain their motor functions and achieve a higher level of independence are less likely to require ongoing care and assistance. This reduces the strain on healthcare resources and minimizes the carbon footprint associated with long-term healthcare services.

Overall, the RGS Ecosystem has the potential for a positive societal impact by improving the lives of stroke patients, while also offering economic benefits through cost-effective rehabilitation solutions. Its environmental and climate impacts are achieved by reducing the need for travel and long-term healthcare services. By addressing these multiple dimensions, the RGS Ecosystem showcases a holistic approach to stroke rehabilitation that considers the well-being of patients, the efficiency of healthcare systems, and the sustainability of our environment.

COMPANY'S POTENTIAL TO CREATE JOBS

In terms of direct job creation, currently, Eodyne counts with 15 FTEs. Five years from now, we project to have a team of 56 people mainly dedicated to marketing and business development (29 people) and technological development (14 people). We plan to enhance our management team by recruiting professionals for key positions such as Operations Director, Commercial Director, and Quality Director. This step is essential to strengthen our leadership and ensure effective decision-making across various functions. Additionally, as we progress towards commercialization, we will focus on developing our capabilities in marketing and sales strategy. To support these efforts, we intend to hire a Business and Market Analyst and a Marketing Manager. As we move forward, our aim is to gradually expand our marketing and sales team. Concurrently, alongside our marketing initiatives, Eodyne will establish its own administrative and accountancy department. This step will allow us to streamline internal processes, enhance financial management, and maintain accurate and up-to-date records. The establishment of this department will be a phased approach, taking place between 2027 and 2029. By doing so, we will build a robust and capable administrative and accountancy force within Eodyne.

Table 18: Job creation (new jobs per year)

2025	2026	2027	2028	2029
3	4	12	4	18

CONTRIBUTION TO THE SUSTAINABLE DEVELOPMENT GOALS

The RGS Ecosystem aims to have a significant clinical and economic impact on healthcare by addressing the challenges in stroke rehabilitation. The project's impact goals are aligned with the Stroke Action Plan for Europe (SAP-E) 2018-2030, which complements the WHO Global Action Plan on noncommunicable diseases (NCDs) 2013–2020, the WHO-Europe NCD Action Plan and the UN Sustainable Development Goals for 2015 to 2030. Specifically, by making rehabilitation more affordable, effective, and accessible, we directly address the following

Figure 11. The Stroke Action Plan for Europe (SAP-E) is a pan-European initiative that was outlined by the European Stroke Organisation (ESO) and the Stroke Alliance for Europe (SAFE). It sets targets to improve stroke care across the continent run until 2030.

UN SDG TARGETS:

- SDG 3 Target 3.4: By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being
- SDG 3 Target 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all
- SDG 3 Target 3.d: Strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks
- SDG 9 Target 9.5: Enhance research and upgrade industrial technologies

And the following **SAP-E TARGETS** (Figure 10):

- Guaranteeing that at least 90% of the population have access to early rehabilitation within the stroke unit,
- Providing Early Supported Discharge (ESD) to at least 20% of stroke survivors in all countries,
- Offering physical fitness programs to all stroke survivors living in the community,
- Providing a documented plan for community rehabilitation and self-management support for all stroke patients with residual difficulties on discharge from 20the hospital.