Smart ICT-solution to cost-efficiently detect atrial fibrillation to Reduce Europe's burden of Stroke

HORIZON 2020

Smart ICT-solution to cost-efficiently detect atrial fibrillation to Reduce Europe's burden of Stroke

Sprawozdania

Informacje na temat projektu Finansowanie w ramach **RedStroke INDUSTRIAL LEADERSHIP - Innovation In SMEs** Identyfikator umowy o grant: 829639 Koszt całkowity € 3 555 382,00 Strona internetowa projektu 🗹 Wkład UE DOI € 2 488 767,40 10.3030/829639 🔼 Koordynowany przez PREVENTICUS GMBH Projekt został zamknięty Germany Data podpisania przez KE 10 Października 2018 Data rozpoczęcia Data zakończenia 1 Listopada 2018 31 Grudnia 2021

Periodic Reporting for period 3 - RedStroke (Smart ICTsolution to cost-efficiently detect atrial fibrillation to Reduce Europe's burden of Stroke)

Okres sprawozdawczy: 2020-11-01 do 2021-12-31

Podsumowanie kontekstu i ogólnych celów projektu

Nine out of ten strokes can be prevented. Measuring cardiac rhythm regularly helps.

Stroke is the second most common cause of death, with 1 million deaths in Europe each year. Stroke survivors are often faced with complex disabilities associated with high health care costs (~€64 billion each year in Europe). The main risk factors for stroke include atrial fibrillation (AF), the most common type of sustained cardiac arrhythmia, increasing the risk of stroke five-fold. AF may come and go and is often not noticed. Its sporadic occurrence is the main reason why it is so difficult to capture. Chances to detect AF with "classic" methods (in office electrocardiogram [ECG] and 24 hour-Holter-ECG) are less than 20%. Furthermore, these methods are costly and not suitable for routine AF screening of large populations. The German SME company Preventicus develops innovative smart health technologies for AF screening with ECG-comparable accuracy – instantly and with a smartphone only. Positive AF cases are verified by Telecare services, followed by a new 14days Holter-ECG-Patch service (for AF confirmation) on demand. Upon early AF diagnosis, therapy can be initiated that prevents strokes. Smart AF detection solutions are a major step forward towards reducing the burden of stroke in Europe.

The overall objective of the RedStroke project is to identify AF earlier and more often than is currently the case in Europe by Standard of Care. For people across Europe to benefit from Preventicus smartphone-based AF detection solutions Preventicus needs to analyse and assess various countries and markets in the EU to prepare and implement these solutions in selected countries and subsequently across the entire EU. The result will be the availability of Preventicus solutions across the EU, the reduction of strokes in the EU, and a sustainable business model for Preventicus and cooperating parties, and highly interesting employment opportunities.

Prace wykonane od początku projektu do końca okresu sprawozdawczego oraz najważniejsze dotychczasowe rezultaty

This summary includes work performed between November 1st, 2018 and December 31st, 2021. The main results achieved are:

- Initial Evaluation of selected European Markets resulted in 8 target countries:
- Germany, Austria, Switzerland, UK, Spain, France, Poland, Netherlands
- Definition of revised target countries for rollout of special care program:
- Germany, Poland, Baltics, Ukraine, Romania, Denmark

(market access opportunities during Corona Pandemic, focus on centralized health care systems/national health systems)

- Development of Business Model for Eastern Europe based on Middle East model
- Market entry preperations for Poland/ Denmark/ Romania/Baltics

• Development of Preventicus Managed Care Program (AF Screening and AF Confirmation) in 6 steps:

- 1) Smartphone AF Screening
- 2) Telecare Quality Control and Verification

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- 3) Referral to local Cardiologist
- 4) ECG Patch for AF Confirmation (14 days)
- 5) Telecare Quality Control, Verification and Report Summary
- 6) Diagnosis through local Cardiologist
- Extension of Managed Care Program to a fully remote telecare concept to account for Corona Pandemic
- Referral Pathway to Telemedical Cardiology centre
- Diagnosis via telemedical connection by a remote Cardiologist
- Setup of Logistics and Support with telemedical partners "Thieme Telecare" and "Herzklinik Ulm Telemedical Centre"
- Composing a special care contract according to SGB V §140a for Germany
- Contract was signed and effective 2019
- -
- all legal data processing and data security issues were considered
- supported by association of Resident Cardiologists in Germany (BNK e.V.)
- important groundwork for implementation in selected EU target countries
- Finalisation of special care contract "RhythmusLeben" in Germany (SGB V §140a)
- Approval of BAS June 2020 after changes to legal contract
- Full Implementation of Preventicus Managed Care Program
- Modification of Telecare Service: technical verification extended to technical and medical verification
- Contract signed Special Care Program "RhythmusLeben" available to all statutory health insurances in Germany
- Roll-out Plan for 2020/2021/2022 defined for Germany
- Onboarding procedure for health insurances defined and ready for implementation in 2020
- Health Economic Evaluation of Preventicus Managed Care Program is showing positive results compared to Standard of Care (Germany)
- Preventicus Managed Care reduces number of strokes
- Preventicus Managed Care reduces health care cost
- Basis for economic evaluation in selected EU target countries
- Health Economic Evaluation published in the journal Health Economics Review in June 2020
- Development of a health economic model for all countries participating in the clinical study
- Health-economic results published in February 2022, to be compared to clinical study results
- Telecare-Center Ulm GmbH is the major Telecare Centre starting in Germany
- Functional and operational as central European Telecare Hub

- Preparation of integration into electronic patient health records, e.g. Sundhed (www.sundhed.dk) and Ezdrowie (ezdrowie.gov.pl)

- Successful Development and Testing of Electronic Invoicing in Preventicus managed Care Program
- Data Safety and Data Security Concept established
- Implementation of Carenet and CareSafe software platforms
- Preparation and Start of the RedStroke Clinical Study
- Study protocol, Ethics Approval, Patient Information and Consent

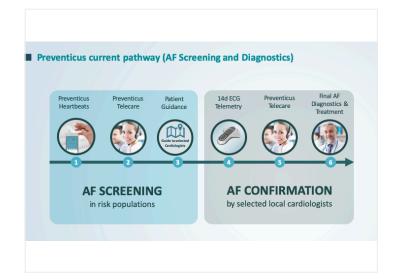
- initially 8 study centers (Basel/CH, Maastricht/NL, Birmingham/UK, Belgrade/SRB, Greifswald/GER, Krakow/PL, Athens/GRE, Budapest, HUN)

- Preventicus Heartbeats is one of the leading health apps in Germany
- over 100,000 downloads in Playstore/Appstore

Innowacyjność oraz oczekiwany potencjalny wpływ (w tym dotychczasowe znaczenie społeczno-gospodarcze i szersze implikacje społeczne projektu)

The RedStroke project is aimed to achieve across the EU by the year 2026:

- 750,000 participants in Preventicus AF Screening
- 30,000 newly identified and confirmed AF cases
- 5,000 avoided strokes (and associated deaths and disabilities)
- Significant Healthcare Cost Reduction because of avoided strokes
- $(> \in 100,000,000 \in 200,000,000)$
- Increased awareness on cardiac health and stroke risks
- Greater Patient Empowerment and Health/eHealth Literacy
- Fully digital Managed Care Program available in EU that can be implemented using telemedicine to work even during pandemics
- Sustainable and Scalable Business Model for Preventicus and its cooperating partners
- Established two complementing business units within Preventicus: Preventicus Medical Devices and Preventicus Managed Care
- Significant Growth of Preventicus as a Company (including # of employees)



Development of Preventicus Managed Care Program (AF Screening and AF Confirmation) in 6 steps

Ostatnia aktualizacja: 23 Listopada 2022

Permalink: https://cordis.europa.eu/project/id/829639/reporting/pl

European Union, 2025