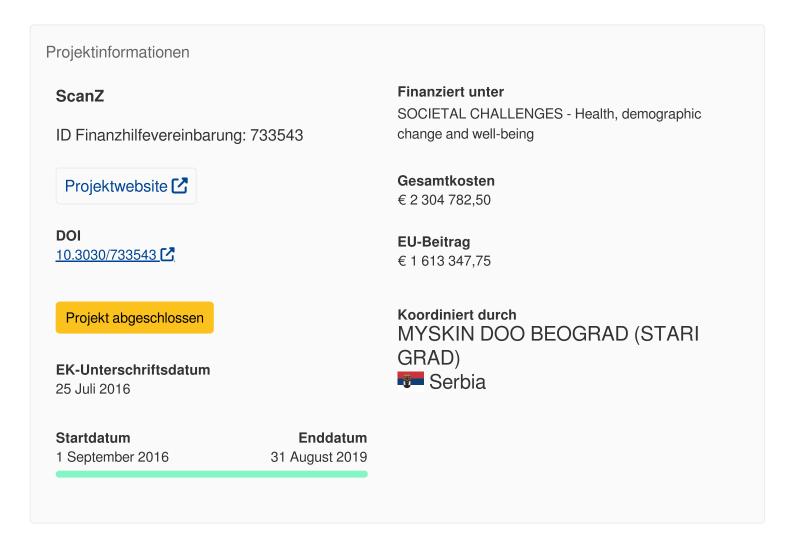
Digital acne assessment tool enabling acne diagnosis in cost and time efficient way



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Berichterstattung



Dieses Projekt findet Erwähnung in ...



Periodic Reporting for period 2 - ScanZ (Digital acne assessment tool enabling acne diagnosis in cost and time efficient way)

Berichtszeitraum: 2017-09-01 bis 2019-02-28

Zusammenfassung vom Kontext und den Gesamtzielen des Projekts

Acne is one of the most common inflammatory dermatoses affecting millions globally. Many effective treatment options are available including prescription and over-the-counter medicines as well as office-based procedures. If acne is not treated early enough or effectively, permanent scarring often ensues. Patients can access information about acne and its treatment from many sources, including magazines and online websites, yet many never seek professional help. In the UK, those who do seek advice may do so from pharmacies or primary care physicians before being referred, if necessary, to dermatology specialists. Over-reliance on antibiotics is still common in many European countries despite warnings in recent evidence-based guidelines of the impact on antimicrobial resistance in the community. Poor adherence and inappropriate prescribing mean many courses of treatment are wasted. Delay in implementing effective therapy which targets inflammation in acne results in unnecessary emotional and physical scarring.

Oral isotretinoin is a highly effective therapy for acne but is currently only available via an appropriately trained dermatologist and as a hospital only prescription due to potential serious adverse effects including teratogenicity and concerns about a causal relationship between the drug and depression / suicidal ideation. Female patients on isotretinoin require monthly follow up as part of a pregnancy prevention programme. More cost-effective care pathways and avoidance of waste are priorities for health service providers. This is all compounded by the fact that the majority of dermatologists use subjective, typically administrative methods of classifying acne lesions. Without objective, quantified data, the treatments are more costly. Severe acne is generally treated with strong drugs, e.g. tetracycline, that can induce serious side effect such as skin irritation, burning or redness, peeling, scaling or discoloration of the skin, increased tendency to sunburn, upset stomach, dizziness, light-headedness or even fetal malformations for pregnant women.

Neglecting to take care of acne may lead to permanent physical effects, like scarring or disfigurement that can also accompany long-lasting psychosocial effects: depression, anxiety, poor self-image and poor self-esteem, or even suicidality. Recent studies had proved that 56% of acne sufferers are more likely to have feelings of isolation and loneliness, 5% of acne patients have considered suicide and 5% have higher unemployment rate compared to adults without acne.

mySkin aims to significantly contribute to a sustainable and cost efficient healthcare system by automating and simplifying the assessment of acne severity. In the PH2 project mySkin seeks to clinically validate, qualify and certify the medical device through a large-scale multicentre medical trial and to develop a high quality and large scale database. The expected outcome of the project is to bring a medically certified MD device to the European market at the end of PH2.

Arbeit, die ab Beginn des Projekts bis zum Ende des durch den Bericht erfassten Berichtszeitraums geleistet wurde, und die wichtigsten bis dahin erzielten Ergebnisse

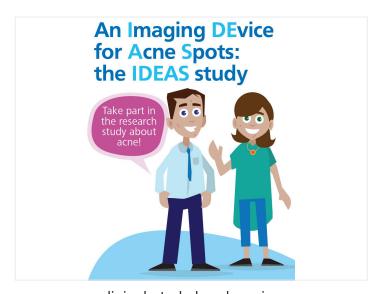
"In the first 12 months of the project the SME beneficiary first focused on the requirements and specifications, the user experience tests, and the software architecture and algorithm improvement. The design of the device and the user interface have been updated, building the ScanZ version suitable for the clinical trials. The first project period was also dedicated for the preparation of clinical trials, including the clinical investigation plans, investigation brochures, case report forms and dealing with the two Ethics Committees. 11 deliverables and 4 milestones have been successfully achieved.

From months 12-30 of the project the SME beneficiary focused on product development: a) hardware development and pro-production prototypes, b) preparation of the software for the evaluation of ScanZ in a clinical trial, c) regulatory filings, preparation of the SME beneficiary for implementation of the Quality Management System (QMS), and d) development of the healthcare economic strategy to assess the impact of ScanZ. Two in-person workshops and training visits have been successfully conducted. 2 deliverables have been successfully achieved. Due to technical and production delays in delivering ScanZ units for the clinical trials as well as hardware complications (identified as risks #1 and #2 in the original grant), the final months were dedicated to restructuring the software portion of ScanZ to mitigate the risks and complete the project within the extended timeline. The last months of the project were also dedicated to restructuring the regulatory approach to ScanZ as a class IIa medical device."

Fortschritte, die über den aktuellen Stand der Technik hinausgehen und voraussichtliche potenzielle Auswirkungen (einschließlich der bis dato erzielten sozioökonomischen Auswirkungen und weiter gefassten gesellschaftlichen Auswirkungen des Projekts)

mySkin proposes an innovative digital acne diagnostic tool, applying new sets of rules, values and a brand new model to the health-care market, which ultimately disrupts the existing traditional skin care market. Up to now, acne assessment was only possible visiting a dermatologist, making it time and money consuming procedure. The ScanZ software solution combined with the point of care device can, for the first time, offer a better and cheaper alternative to the millions of acne sufferers and thousands of dermatologists. ScanZ is an easy-to-use handheld imaging device enhanced with a software application (smartphone/tablet) to monitor and analyse acne. ScanZ enables accurate diagnosis, tracking and monitoring at hospitals or remotely from home. mySkin aims to bring ScanZ out to the Health Care market at a reasonable price and in an easy-to-use manner, offering improvements to health and living conditions of acne sufferers. ScanZ will enable a more sustainable and efficient healthcare system, significantly reducing doctor's workload and waiting time in clinics. The innovate solution will collect and store all acne records in its digital data bank, which will be open to the doctors and researchers for use in the analysis of acne and for raising further awareness and diagnosis, as well as for the future medical research. This data will save medical organizations, pharma companies and national healthcare institutions millions of euros by not having to run clinical trials and collect the data themselves. It will also enable the first long-term quantified view of acne treatments.

By the end of the project, ScanZ will have implemented the first step to the overall platform which is the Hospital information system, a class IIA device that enables nurse practitioners to conduct followups of Isotretinoin patients using a fully digital approach.



clinical-study-brochure.jpg

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