



Studies&Me®

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Celebrating a Remarkable Recruitment Effort!

At Studies&Me we are very proud to have reached our recruitment targets for the clinical study of Coegin Pharma AB's potential new topical treatment of actinic keratosis.

This milestone brings us one step closer to achieving a better treatment for people suffering from this specific pre-cancerous skin condition.

What does success in this case look like?

Within only 7 weeks and 3 days of social media advertising, we succeeded in reaching our recruitment target and the study is now running full speed ahead.

In addition to our great recruitment efforts, our study site managed to randomize the required 60 participants needed to complete the clinical study.

Our exceptionally fast recruitment took place despite the COVID-19 pandemic and busy Christmas times. In our marketing forecast, we had envisioned that recruitment of participants with a sun-influenced condition could have an impact on the efficiency of the recruitment due to the dark, cold days. However, we saw the exact opposite; because the season unexpectedly did not prevent patients from seeking help and solutions to their skin conditions.

The study included a diverse group of participants representing an almost equal percentage of men and women (55% men and 45% women were randomized).

The age group of the participants varies from 45 to 80 years of age securing increased diversity in study participants. The great extent of participant diversity increases the chances of collecting diversified study data, enabling us to achieve more representative study results.



The remarkable results speak for themselves

Below we have compared the COAK study with a conventional phase II actinic keratosis study. Since the LFX435 study had a longer duration, we can not use these numbers to directly compare recruitment speed, but we can give you an idea of our remarkable number of study participants and sites.

As you can see below, the LFX435 study employed 10 sites to randomize 82 participants. In our COAK study, we only utilized 1 site to randomize the required number of 60 study participants.

Not only has the target been met; our dedicated team has also managed to recruit a diverse pool of participants that leads to promising representative data across age and gender.

AK Study	Study Duration	Number of Participants	Number of Sites
COAKS	Study start date: November 2nd 2021 Expected study completion date: March 2022 Total duration: 4 months	60 participants	Denmark: 1 Department of Dermatology, Bispebjerg Hospital, Copenhagen Total number: 1
Safety, Tolerability, and Efficacy Study of LFX453 in Actinic Keratosis Patients	Study start date: March 5th 2015 Study completion date: January 27th 2016 Total duration: 10 months 22 days	82 participants	Denmark: 1 UK: 1 Iceland: 1 Germany: 6 Austria: 1 Location in DK: Novartis Investigative Site, Copenhagen NV Total number: 10

The article is written in collaboration between Coegin Pharma and Studies&Me.

About the Clinical study

Studies&Me is conducting the clinical study for Coegin Pharma AB to test a promising topical treatment of early-stage skin cancer, actinic keratosis (AK). The study is a combined phase 1/2a interventional study led by principal investigator, professor Merete Hædersdal at Bispebjerg Hospital of Copenhagen, Denmark.

The study includes patients eligible for topical treatment with AVX001 gel in different doses or placebo with the purpose of investigating its safety and efficacy. The end goal is to develop a new topical treatment that satisfies patients' needs for a safe, efficient and practical treatment of their condition.

The clinical study is conducted across all of Denmark and includes 60 participants. It is designed with as few in-clinic doctor visits as possible and a high degree of remote data collected by the patient on their own mobile device through a specific study application that is designed for the participants to engage in the study. Hence, this allows patients across Denmark to participate in the study at their own convenience.

About Actinic Keratosis (AK)

AK is a common skin condition that is caused by long-term sun exposure. AK lesions are presented as small, red, rough, scaly flat spots, which feel like patches of dry skin and are a common precursor (early-stage) to skin cancer.

AK is considered a chronic condition as most patients experience that the lesions return over time. AKs increase the risk of developing skin cancer since it can likely develop into Squamous Cell Carcinoma (SCC), which is a common and invasive type of skin cancer.

The occurrence of AK is caused by the skin's exposure to the ultraviolet radiation of the sun over a lifetime. While the condition may occur in young adult patients, it is more common with elderly patients who have spent more time in the sun.

There is no clear recommendation on current guidelines for a preferred treatment approach for AK lesions. The condition is mainly treated with cold therapy, photodynamic therapy or topical treatment. As a result there is an unmet medical need for new treatments for use in the treatment of patients with AK.

About Coegin Pharma AB

Coegin Pharma is a biotech company focusing on development of small molecule-based drug candidates for treatment of cancer. The therapeutic platform is based on selective inhibition of the key enzyme cPLA that attenuates inflammations and uncontrolled cell growth. The enzyme has passed a thorough preclinical and clinical validation and is a relevant therapeutic target of a series of cancers and inflammatory diseases. The

company drives the development from identifying a promising drug candidate to phase 2a clinical studies indicating a "proof of concept". Upon proof of concept, the drug candidates are sold to international operators/pharmaceutical companies.

About Studies&Me® A/S

Studies&Me is Europe's first fully digital contract research organization to set new standards in clinical research by delivering end-to-end solutions for decentralized clinical studies. With a legacy in pharma and health technologies, Studies&Me works to digitalize treatment development across all stages; from recruitment to study completion.

Studies&Me collaborates with partners across the globe to advance human health and achieve our mission:

To advance treatment development.

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