

Studies&Me

Studies&Me to personalize treatment development as Europe's First Virtual CRO

After four years, LEO Innovation Lab launches Studies&Me™ as an independent Virtual Contract Research Organisation, gathering all stakeholders in treatment development under one roof to set new standards for clinical research

Copenhagen, Denmark. 2020 has become the year where industries across the world have had to adapt to a new reality in light of the ongoing COVID-19 pandemic. The clinical trial industry is no exception. With social distancing limiting mobility and face-to-face interactions, clinical trial operations are forced to adapt to a remote setting, using digital technologies.

However, the need for change was evident way before the global health crisis hit, as conventional clinical research is in need of digitization. Today, the journey from clinical trial to treatment is long, costly, and suboptimal. Recruitment, adherence, and retention are some of the primary barriers followed by high trial complexity. As a result, it now takes up to 12 years for a new treatment to become available to those who need it.

From within LEO Innovation Lab, Studies&Me set out to change this four years ago. Since then, Studies&Me has been working on digitizing the clinical research process across all stages from recruitment to trial completion by exploring, testing, and validating new methods for conducting smarter, faster, and more accessible clinical trials.

Now, Studies&Me is ready to come into its own as Europe's first virtual contract research organisation, gathering all stakeholders under one roof, including its own investigators in an online hospital setup.

Studies&Me to personalize treatment development

For long, clinical research has suffered from a convenience problem. Participation can be a demanding task, requiring a number of visits to local study sites for clinical appointments. In the US, only 2% of the eligible population participate in clinical trials. Furthermore, participants have to show up at the trial site 11 times within 6 months on

average¹ - often during working hours. As a result, up to 40% of participants drop out throughout the study.

A core focus for Studies&Me is to leverage digital technologies for more convenience and better data collection by allowing people to participate in clinical trials from the comfort of their home using their own smart devices, thereby increasing flexibility and the participants' autonomy.

Introducing digital tools can facilitate the capture of real-time data outside the clinic rather than relying solely on snapshots of the patient's condition from in-clinic assessments. Not only do remote solutions reduce the need for physical consultations; they also provide more detailed insights about the individual participant as well as allowing for more diverse patient populations to benefit from trial participation. Ultimately, this can build the foundation for more personalized medicine.

"We believe the future of clinical research is patient- and data-driven. We want to personalize treatment development by turning clinical operations upside down to ensure that the trial design and technology fit into the everyday life of the patient - not the other way around. With this approach, and in close collaboration with leading physicians, we can accelerate treatment development and achieve clinical research of higher data quality by leveraging real world data from the patients, using devices they already have at their disposal at home, such as their smartphone. This will also provide the treating physician a unique opportunity to follow their patient in real time," says John Zibert, CEO at Studies&Me and former Chief Medical Officer at LEO Innovation Lab.

New digital solutions for clinical trials

The new Studies&Me will focus on developing end-to-end solutions for decentralized trials while testing and validating novel approaches to decrease trial complexity, conduct remote severity assessments, and address core challenges within the clinical trial industry.

Together with Novo Nordisk, LEO Pharma, Bispebjerg Hospital, and Trial Nation, Studies&Me is launching two studies with eczema and diabetes patients in August, and one in early 2021 to test a platform for clinical trials, running on the patients' own smartphones.

With support from their Online Hospital of board-certified dermatologists, endocrinologists, and specialists in general medicine, Studies&Me is also developing and testing new solutions for assessing clinical outcomes from patients remotely using

¹ Virtual Clinical Trials: Perspectives in Dermatology (2019), Bispebjerg Hospital, LEO Innovation Lab, University of Copenhagen. <https://www.karger.com/Article/Pdf/506418>

an advanced always-online tablet-based screening system, where doctors can evaluate skin lesions and the real-time status on blood sugar levels from anywhere in the world.

Furthermore, Studies&Me recently ran a fully virtual study, addressing the significant recruitment barriers, poor adherence, and dropouts, which increase costs and negatively affect trial outcomes. Individuals with atopic dermatitis were recruited online for an 8-week study where they took weekly photographs of their lesions using a skin tracking app to assess disease severity remotely. They also completed online questionnaires. Upon completion of the weekly tasks, participants were rewarded with personalised lifestyle reports, based on their DNA. Ultimately, this led to a 96% retention rate, and more than 90% of all study tasks were completed², demonstrating the benefit of deploying new retention and adherence measures and adapting to a virtual setting to accommodate patient needs.

"These numbers for retention and adherence are truly impressive and something we only rarely see in conventional clinical research. Furthermore, the platform improved our capability to see more patients, optimizing the sparse time we have to conduct clinical research", says professor and chief physician Simon Francis Thomsen, Bispebjerg Hospital, University of Copenhagen, Denmark.

² High adherence and low dropout rate in a virtual clinical study of atopic dermatitis through weekly reward-based personalized genetic lifestyle reports (2020), Bispebjerg Hospital, LEO Innovation Lab, University of Copenhagen, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7332076/pdf/pone.0235500.pdf>

About Studies&Me

Studies&Me is a European-based virtual contract research organization (V-CRO), specializing in delivering end-to-end solutions for conducting decentralized trials. With a legacy in pharma and health technologies, Studies&Me is working to digitize treatment development across all stages; from recruitment to trial completion.

Studies&Me was initially conceived in 2016 as a platform to facilitate online patient recruitment and qualification for clinical trials at LEO Innovation Lab, LEO Pharma's innovation unit.

In August 2020, Studies&Me was relaunched as an independent organisation to set new standards for clinical research by tapping into the unmet potential of emerging technologies and ever-expanding volumes of digital data.

The organisation is based in Denmark and collaborates with partners across the globe to advance human health and achieve their mission: To personalize treatment development.

About LEO Innovation Lab

LEO Innovation Lab was established in 2015 as an independent innovation unit of Denmark's oldest pharmaceutical company LEO Pharma. Being owned by a foundation, LEO Pharma has no shareholders to consider, and all profits are reinvested into new research to help patients. The innovation lab addresses global healthcare challenges with digital technology designed to alleviate specific pain points experienced by patients or doctors within dermatology.

Since 2018, LEO Innovation Lab has focused on two key strategies: leveraging machine-learning technology to diagnose skin conditions to a high degree of accuracy, and digitizing treatment development across all stages in collaboration with research partners across the world to achieve global impact for healthcare.

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