A Successful Collaboration results in End of Procedure (EOP) for the paediatric indication for Sedaconda (isoflurane)

We at LINK Medical are filled with pride and gratitude as we successfully conclude the IsoCOMFORT study. The successful completion of this study was made possible due to the great teamwork between LINK Medical and Sedana Medical.

“Through close collaboration and flexibility, we managed to create a productive and valuable relationship between the teams and deliver good results”, said Sharareh Elfversson, Director of Clinical Operations, at LINK Medical.

In 2019 LINK Medical was chosen by Sedana Medical as CRO to run the IsoCOMFORT trial, a randomised active-controlled assessor-blinded study comparing the efficacy and safety of sedation with inhaled isoflurane administered via the company’s medical device Sedaconda ACD-S, with intravenous midazolam in mechanically ventilated patients aged 3 to 17 years old. The study was conducted with the goal of securing data exclusivity and market protection for the Sedaconda® (isoflurane)’s main indication in adult patients, and to obtain approval for the use of Sedaconda (isoflurane)for sedation of mechanically ventilated children in intensive care.

The study was run at 28 sites in 5 countries across Europe and ended successfully in March 2023. The Clinical Study Report was signed in October 2023. Based on the results of the IsoCOMFORT study, Sedana Medical filed a submission for a pediatric indication in December 2023 and the EOP was reached on 13December 2024.

For more information about the IsoCOMFORT study, please visit [https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-000578-31/results].

About LINK Medical

LINK Medical is a leading life science service partner, providing experts, flexible services, and innovative technologies for the pharmaceutical and medical device industries.
LINK Medical has over 25 years of experience in offering end-to-end solutions across all product development areas, from pre-to post-marketing.

Our services include CRO, Clinical Operations, Project Management, Biometrics, Regulatory Affairs, Chemistry Manufacturing and Controls (CMC) development, Safety & Pharmacovigilance, Medical Monitoring, Medical Writing, Quality Assurance (QA), Market Access, and Real-World Evidence.

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