

Advancing nano-rare disease treatment with Syde technology in clinical trials

(1) About Sysnav Healthcare

Sysnav Healthcare developed Syde®, a clinical-grade wearable device used for precise, continuous evaluation of ambulation and upper limb function in real life. Synav Healthcare and its partners are the first to qualify a digital endpoint (SV95C) with the European Medicines Agency as a primary endpoint.



Sysnav Healthcare aims to unlock the potential of real-world data in the medical field by adapting extremely precise motion-capture solutions to the needs of healthcare professionals and patients. Sysnav's Syde technology has been deployed in over 80 clinical trials for over 15 indications.



- Nano-rare diseases are very rare disorders that affect fewer than 30 patients globally.
- Limited treatment options and development programs exist for patients with these diseases, representing an area of unmet medical needs.
- However, due to the wide range of disease symptoms and the severity of the disease, demonstrating a drug's effectiveness is even more complex for these extremely rare conditions. These conditions often have no or limited natural history data to inform possible benefits.

The challenge

- Conventional patient outcomes in clinical trials can lack the robustness and accuracy needed at the patient population level. A limitation is the inability to capture real-world functional changes in patients with sufficient statistical power to demonstrate the effectiveness of experimental therapies.
- Defining treatment goals and outcome measures is vital, particularly with fewer than 30 patients per condition, where individual clinical changes become the focus.
- In addition, N-of-1 trials require added sensitivity to observe changes in movement in patients, where small movement changes early in dosing could signal that the medicine may be having an effect.
- The sDHTs most useful for an N-of-1 clinical trial require high-precision hardware, specific sensor placement, highly sophisticated calibration methods, and the potential to capture real-world data in the home setting.



Building the **Business Case** for Digital Endpoints



Case study





- The n-Lorem Foundation is a non-profit organization creating personalized treatments for nano-rare disease patients. They developed a personalized experimental antisense oligonucleotide (ASO) medicine for a KIF1A-associated neurological disorder (KAND) patient.
- For the N-of-1 clinical trial sponsored by the n-Lorem Foundation, Sysnav Healthcare deployed the Syde platform, which includes:
 - \circ The Syde wearable collects continuous physical activity data from the patient
 - Analytics services and unique 3D reconstruction of patient physical function based on the data from Syde
 - End-to-end clinical operation services, including logistics, wear compliance, site support, and data management

The impact

- The centimetric precision allows continuous monitoring and evaluation of the patient's daily functioning during the clinical trial.
- Syde can detect features not yet probed through traditional methods (e.g., ataxia, swing time in real life, fatigability, walking perimeters). Its ability to detect these subtle variations enables earlier identification of improvements or declines.
- Continuous data provides faster feedback, helping physicians adjust treatments more quickly. Unlike traditional research methods, which take weeks or months to analyze, Syde's data is available in real time.
- The Syde platform can leverage the pre-existing normative datasets to compare the disease evolution to age and gender-match populations.
- Patient comfort: Syde's remote monitoring reduces in-person visits. This flexibility reduces the logistical burden on the patient and enhances patient satisfaction during the clinical trial.

Sysnav's raison d'être is to enable medical progress through meaningful data. We are proud and honored to support the n-Lorem Foundation in their quest toward developing a treatment for Kinesin family member 1A (KIF1A) Associated Neurological Disorder (KAND)."

— Damien Eggenspieler Sysnav Healthcare Director



