

PEDIATRIC ASTHMA

Ludocare demonstrates the effectiveness of its Digital Therapeutic, JOE, in reducing the number of severe asthma exacerbations in children aged 7 to 11 years.

Lyon, France – June 12, 2025 – Ludocare, a Lyon-based pioneer in Pediatric Digital Therapeutics, announces positive results from its phase 3 randomized clinical trial, Asthma JOECARE, **in children aged 7 to 11** suffering from persistent asthma, with a reduction in the number of severe exacerbations (asthma attacks).

Pediatric asthma: An underestimated public health issue

Asthma is the most common chronic disease among children, affecting over one in ten in France¹. This complex and often poorly controlled condition significantly impacts:

- **Children's health:** frequent asthma attacks can cause irreversible lung damage and be life-threatening.
- **School attendance:** asthma is the leading cause of school absenteeism in France².
- **Quality of life:** asthma disrupts sleep, limits physical activities, strains family and social relationships, and generates mental burden for parents.

Despite the availability of inhaled treatments aimed at controlling symptoms, their effectiveness is often undermined by poor adherence, incorrect usage of inhalers, and inadequate inhalation technique³⁻⁴. In 2015, more than 42,000 asthma-related hospitalizations were recorded among children under 15¹.

Learning to manage the disease early is essential to prevent serious complications.

In response, Ludocare has developed a breakthrough innovation: **JOE**, a Digital Therapeutic combining a connected health companion for children and a mobile application for parents. **JOE supports families in the daily management** of asthma by:

- Improving treatment adherence,
- Teaching proper device use and inhalation techniques, helping children take ownership of their treatment in a playful way,
- Reducing parents' mental load with a digital tool that fits seamlessly into daily life.

The JOE Digital Therapeutic does more than just send medication reminders: it provides education on proper use and inhalation technique, thereby boosting adherence and **improving drug delivery efficiency, which results in better asthma control.**

Clinical evidence supports efficacy.

The **Asthma JOECARE** study (NCT04942639), conducted across 17 hospital and outpatient centers in France, included **213 children with asthma aged 4 to 11**, followed over a 12-month period. Participants were randomized into two groups:

- Control: standard maintenance treatment,
- Intervention: standard treatment + JOE, Ludocare's Digital Therapeutic.

The study demonstrated a clinically relevant and statistically significant **reduction in the number of severe exacerbations** in children aged 7 to 11, confirming JOE's therapeutic benefit for this age group.

Ludocare meets three key challenges

Through the Asthma JOECARE study, Ludocare addressed three major challenges, underscoring its commitment to transforming pediatric asthma care:

➤ High methodological standards

The study was designed according to the ICH (International Council for Harmonization) guidelines for pharmaceutical clinical trials: randomized, controlled, and multicenter. This level of methodological rigor grants the results rare scientific credibility in the field of Pediatric Digital Therapeutics.

➤ Diversity of investigator practice

The trial involved clinicians from both hospital and community practices, reflecting the diversity of care pathways for children with asthma. This city-hospital network enhances the external validity of the study results.

➤ Robust pediatric recruitment

With over 213 children aged 4 to 11 with persistent asthma, the study represents a notably large and representative pediatric cohort for clinical research.

Toward reimbursement in France and Germany

Backed by this clinical evidence, Ludocare is pursuing reimbursement procedures for JOE as the first reimbursed Digital Therapeutic for pediatric asthma in both France and Germany. This would mark a significant step toward greater equity in access to care for children with asthma.

“The Asthma JOECARE study clinically demonstrated the positive effect of a digital therapeutic in reducing asthma attacks. Beyond measurable outcomes, we observe essential additional benefits in our young patients daily: improved therapeutic education, better care experiences, and a strong positive reinforcement mechanism that cannot be captured in a clinical trial.”

Dr. Kévin ARLAUD, Pediatric Pulmonologist, Aix-en-Provence

“Beyond quantitative results, the children’s and families’ feedback highlights the perceived positive impact of being supported by Joe. Many stories show how this tool improved their daily experience of the disease, fostered greater treatment engagement, and changed how they perceive their condition. For many, the ‘little extra’ is no longer the disease—but the kind, playful presence of their robot companion.”

Dr. Céline CHANELIERE, Pediatric Pulmonologist, Lyon

“These results represent a key milestone for Ludocare and validate the contribution of digital therapeutics in the management of pediatric asthma as a complement to pharmacological treatments. Our therapy, with no contraindications, drug interactions, or side effects, helps optimize care for children with asthma. It also paves the way for a more personalized approach to patient management. These results further support our reimbursement strategy in France and Germany.”

Alexandra de la Fontaine, CEO of Ludocare

About Ludocare

Founded in 2017 in Lyon, **Ludocare** develops digital therapeutics for children with chronic diseases. By combining medical effectiveness and playful learning, Ludocare empowers children to manage their health early on and enjoy a better long-term quality of life. Its first Digital Therapeutic, JOE, is dedicated to children with persistent asthma.

Sources

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2. Ameli, *Understanding asthma in children over 3 years old*, November 2022, <https://www.ameli.fr/yvelines/assure/sante/themes/asthme-enfant-plus-3-ans/comprendre>
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4. Haute Autorité de Santé, *Proper Use of Inhaled Medications in Asthma – Summary Sheet*, 2004, https://www.has-sante.fr/upload/docs/application/pdf/fiche_de_synth_350se_asthme.pdf