PRESS RELEASE

SPIOMET4HEALTH

Polycystic Ovary Syndrome (PCOS) in adolescents and young women: towards a pathophysiology-guided treatment

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SPIOMET4HEALTH enters its final year with a clear course towards the first treatment for polycystic ovary syndrome

- With patient recruitment and intervention completed, the consortium is now focusing on data analysis and exploring the feasibility of the treatment.
- The results expected in 2026 could mark a milestone in the clinical and metabolic management of PCOS in adolescents and young women.

Polycystic Ovary Syndrome (PCOS) is one of the most common endocrine–metabolic disorders in adolescents and young women, affecting approximately ten percent of this population. Its manifestations —such as menstrual irregularities, excess body hair, acne, or impaired fertility— can significantly impact long-term health. However, despite its prevalence and impact, there is currently no specific treatment for PCOS, forcing healthcare professionals and patients to rely on therapies that address individual symptoms rather than the root cause of the condition.

In this context, **the European project SPIOMET4HEALTH is working towards the development of the first treatment specifically designed for PCOS**. The project, which has been underway since 2021, aims to **generate robust scientific evidence that could transform the future management of this condition and improve patients' long-term quality of life**. To this end, a new therapeutic combination has been designed and evaluated through a clinical trial conducted in six countries (Spain, Austria, Norway, Italy, Denmark, and Turkey). Combined with an appropriate lifestyle intervention, this therapy seeks to restore endocrine–metabolic function in young women with PCOS.

The project, which is scheduled to conclude in December 2026, begins its final year having consolidated key milestones and with a clearly defined, results-oriented work plan.

Clinical progress, European cooperation, and solid scientific evidence

Throughout 2025, SPIOMET4HEALTH achieved key advances. Participant recruitment was completed across all clincal trial sites, and more than 80% of the enrolled young women have completed their assigned treatment or intervention. **The clinical trial involved 312 adolescents and young women aged 12 to 24 diagnosed with PCOS**, all of whom received close medical follow-up from the project team throughout the process, along with lifestyle recommendations to support their well-being and management of the syndrome.

SPIOMET4HEALTH is a phase II clinical trial aiming to develop a single tablet that combines three medications —spironolactone (SPI), pioglitazone (PIO), and metformin (MET)— which have already demonstrated benefits in the management of PCOS in pilot studies. To **assess which formulation is the most effective and safe**, the trial compares different combinations and doses of the three drugs with a placebo group. As a result, some participants receive placebo, while others receive different doses of SPI, PIO, and MET. This design makes it possible to analyse the

body's response to each variant and determine which offers the best outcomes in terms of ovulation, endocrine parameters, and improvement of metabolic alterations.

Once these activities were completed, the consortium was able to **collect the essential clinical data and move forward with preliminary analyses and data quality validation** —an essential step to ensure the robustness of the study.

According to the project coordinator, Dr. Lourdes Ibáñez from Hospital Sant Joan de Déu in Barcelona: "SPIOMET4HEALTH is now entering a crucial period. Thanks to the commitment of the consortium and the young women who participated, we are closer to obtaining solid evidence on a potential new therapeutic pathway for PCOS. This project represents an exceptional European effort to improve the future health of millions of women".

On 29 and 30 September 2025, the consortium held its General Assembly Meeting, marking the conclusion of PCOS Awareness Month. The hybrid-format meeting brought together all project partners to review scientific progress, share preliminary results, and coordinate the steps for this final year. Beyond the technical presentations, the meeting was a valuable opportunity to exchange ideas, strengthen collaboration, and reinforce team spirit within the consortium.

2026 to-dos: final results and next regulatory steps

SPIOMET4HEALTH begins 2026 with a defined work plan and a well-established operational structure. The study databases are closed or in the final stages of monitoring and validation, a key process prior to the start of the final analyses. Collaboration among the scientific teams at the participating centres enables coordinated preparation for the next phase of the project: a comprehensive evaluation of the effects and safety of the investigated treatment.

During this final year, the consortium will focus on completing the efficacy and safety analyses that will determine the therapeutic potential of the evaluated combination. In addition, **assessments of the clinical, scientific, and regulatory feasibility of the treatment** will be carried out, along with the preparation of the final reports for the European Commission. The project will also advance its results exploitation strategies and regulatory preparation, while continuing communication activities and knowledge transfer to healthcare professionals, the scientific community, and society at large.

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More information at https://spiomet4health.eu/