

## Identifai-Genetics Launches Its First U.S. Clinical Trial, Led by Professor Ronald Wapner

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Identifai-Genetics, developer of unique AI-based solutions for non-invasive fetal DNA sequencing, announced today that it has launched its first US clinical trial, in collaboration with **Columbia University** and the **Columbia University Irving Medical Center** in New York.

Identifai is revolutionizing pregnancy safety and prenatal testing by offering the first solution for non-invasive whole-genome sequencing of the fetus, using a blood test from the mother during the first trimester of pregnancy. Identifai's platform and diagnostic tools enable early detection of the whole spectrum of fetal genetic disorders in an accessible, cost-effective and risk-free manner.

Identifai's US clinical study is aimed at demonstrating the performance and effectiveness of the company's novel technology in real-world scenarios within the United States. Additionally, the study will serve as an analytic validity study, marking a prominent milestone in the regulatory pathway of the company's first product line.

The study cohort will include 100 pregnant women; its main arm will focus on anomalies known as *autosomal recessive monogenic disorders*. In these disorders, a gene is affected by distinct pathogenic variations in the DNA of the mother and the father. A single variation might not cause a disease, but inheriting the variations from both parents could lead to a severe fetal anomaly. These scenarios represent a significant segment of fetal genetic diseases, with prevalence of at-risk couples reaching 5% in specific populations.

The principal investigator in the study is world-renowned Professor Ronald J. Wapner, Director of Reproductive Genetics and Professor of Obstetrics and Gynecology at Columbia University Irving Medical Center. Prof. Wapner is a pioneering figure in prenatal testing, having played a pivotal role in the development and initial clinical trials of chorionic villus sampling procedures and chromosomal microarray analysis. The overseeing management will be done by Jessica Giordano, Assistant Professor of Genetic Counseling, the Associate Director of Women's Genetics Research at Columbia University and an investigator in the study.

Dr. Amir Beker, Identifai's CEO, stated: "We take immense pride in launching Identifai's inaugural US clinical trial in partnership with Columbia University, spearheaded by the

esteemed Prof. Wapner, a global leader in the NIPT field. This study marks a critical milestone in

transforming Identifai's technology into a clinical offering accessible to millions of women in the US and across the globe".

## About Identifai-Genetics

Identifai-Genetics, a cutting-edge digital bioinformatics company, was founded in 2021, based on the ground-breaking academic research by Prof. Noam Shomron and Dr. Tom Rabinowitz, from Tel Aviv University. The company has raised over \$6M in equity investments and R&D grants.

The company's co-founders include Shizim Innovation Center, led by Mr. Yossi Bornstein, who serves as Identifai's chairman, as well as Prof. Noam Shomron (CSO) and Dr. Tom Rabinowitz (CTO). The company is headed by Dr. Amir Beker, co-founder and CEO.

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