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EVALUATION OF THE EFFICACY OF INCLISIRAN FOR THE TREATMENT OF PRIMARY HYPERCHOLESTEROLAEMIA O MIXED DYSLIPIDAEMIA: ANALYSIS OF AIFA MONITORING REGISTERS

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Keyword: PCSK9, Inclisiran, snRNA, Hypercholesterolaemia, AIFA monitoring registers

Background and importance

Hypercholesterolaemia is a significant challenge in the management of cardiovascular disease, with considerable implications for public health and the National Health System. Inclisiran, a synthetic oligonucleotide complementary to the mRNA encoding the PCSK9 protein, has the potential to reduce intra-individual variability in LDL-C levels over time. With its twice-yearly administration, it can offer an optimal solution to ensure adherence to therapy, ultimately lowering the risk of cardiovascular events in high-risk patients.

Aim and objectives

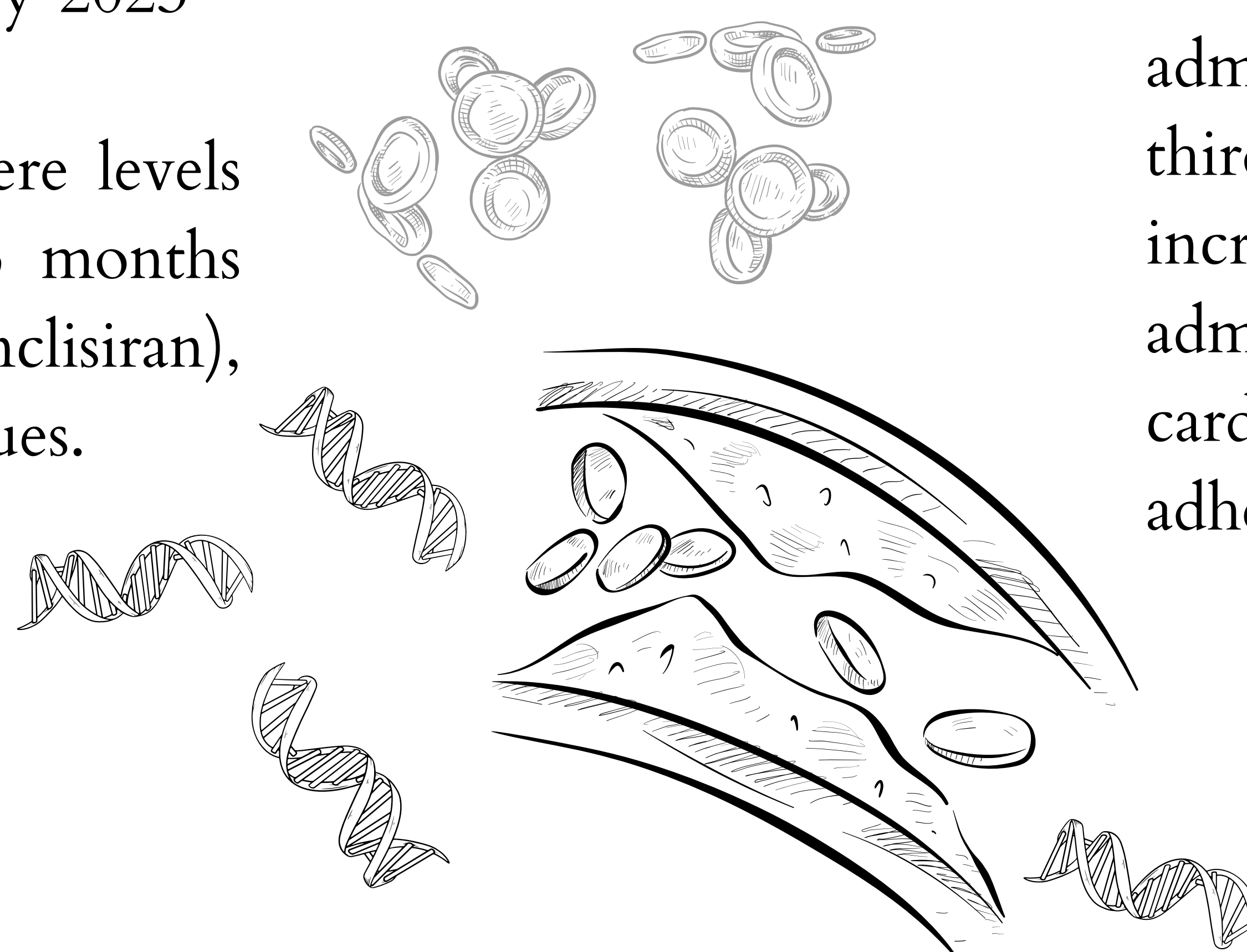
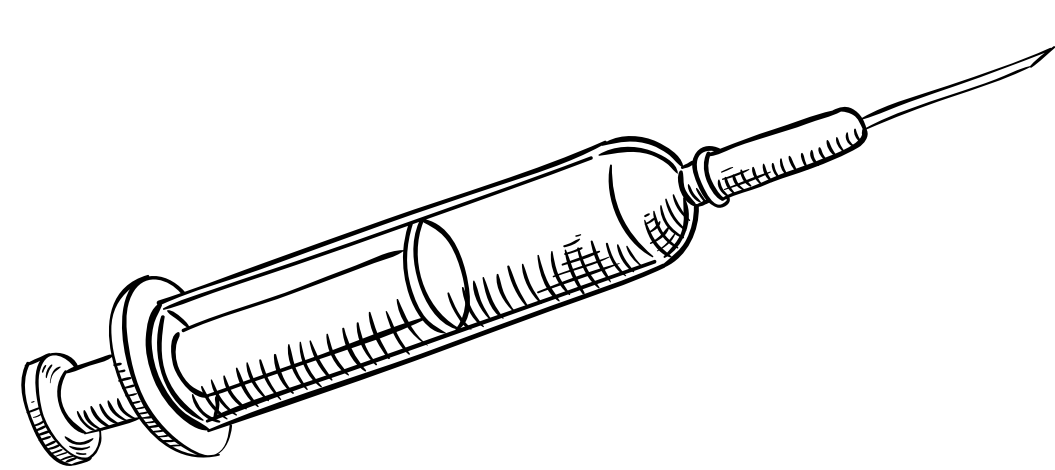
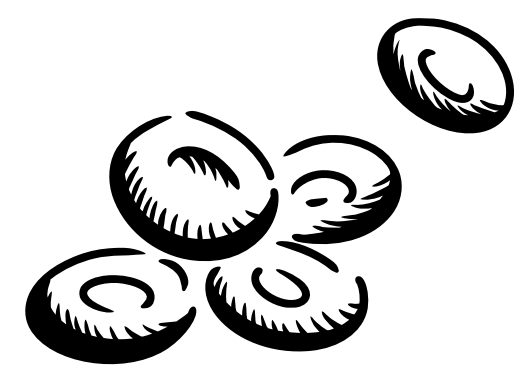
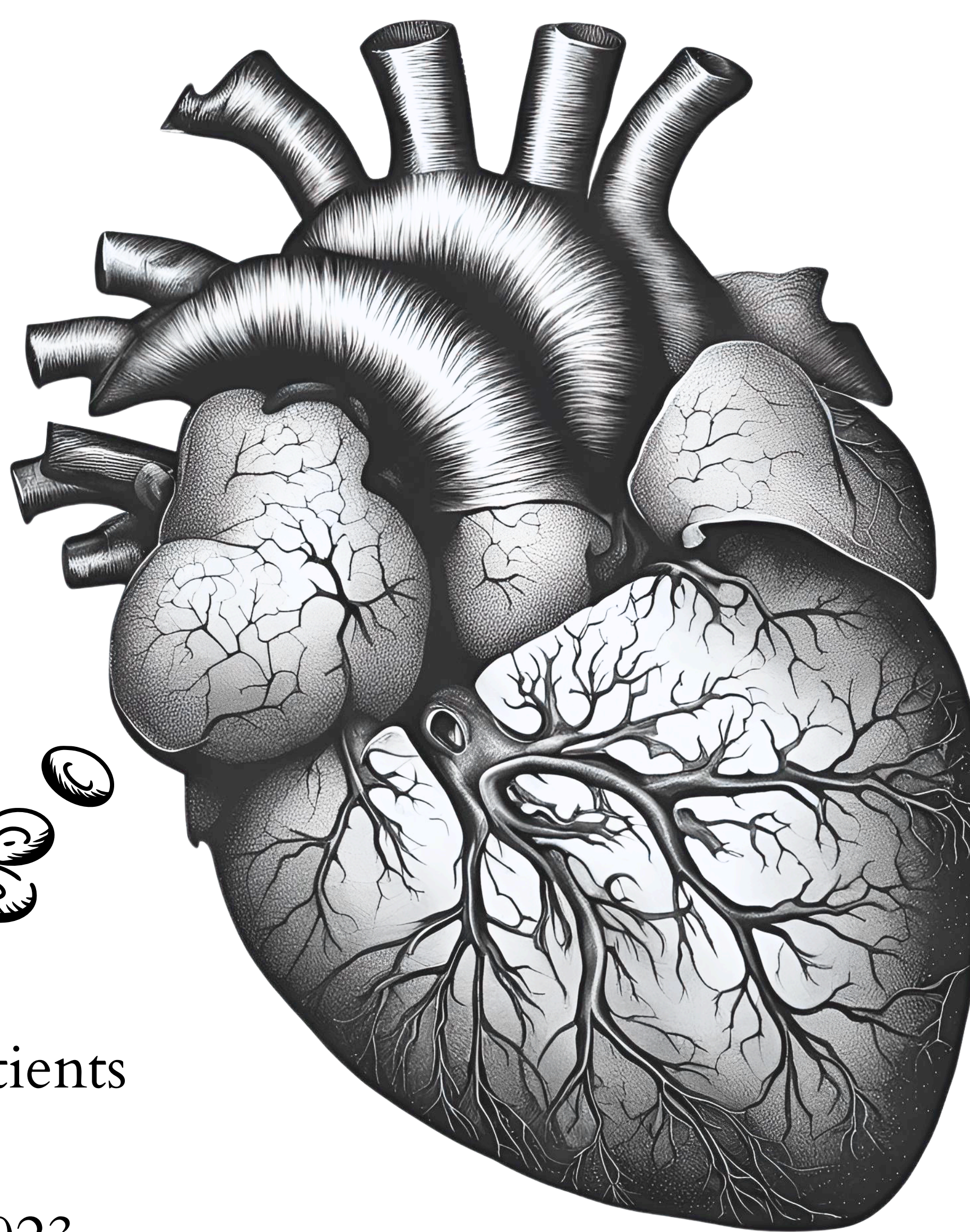
This analysis aims to assess the efficacy of inclisiran in patients suffering from primary heterozygous familial hypercholesterolemia (HeHF), non-familial hypercholesterolemia (noHF) or mixed dyslipidemia (MD).

Material and methods

AIFA Monitoring Registers of patients treated with inclisiran were analyzed.

The considered period was January 2023 - September 2024.

The indicators of effectiveness were levels of LDL-C and HDL-C after 15 months (i.e. three administrations of inclisiran), compared to the pre-treatment values.



Results

After evaluating 168 AIFA Monitoring Registers, 35 patients (74% male, 26% female) with available follow-up data at 15 months were included.

The mean age of the cohort was 66 years (range: 45-81), with 16 patients suffering from MD, 17 from noHF, and 2 from HeHF.

The efficacy of Inclisiran is promising, with significant reductions in LDL-C levels: 24% at 3 months, 30% at 9 months, and 46% at 15 months. Average LDL-C reductions were 42.7 mg/dL after the first two administrations and 64.8 mg/dL after the third. Furthermore, HDL-C levels increased, rising from 7% to 19% after 3 administrations of inclisiran. No cardiovascular events were reported and adherence to the treatment was high.

Conclusion and relevance

In the considered sample of patients treated with inclisiran, a consistent reduction in LDL-C levels over time has been proven, with peak efficacy (-46%) observed after three doses, alongside a steady increase in HDL-C levels, thus contributing to prevent cardiovascular risks. The six-month dosing schedule was a strong point that increased therapeutic adherence.

