patients with arrythmias. There is room for improvement, and the clinical pharmacist could collaborate in optimisation, improving the final results, and avoiding complications and drug related adverse effects. Creating a drug dispensing protocol in addition to a comprehensive clinical evaluation for antiarrhythmic therapy, taking all the risk factors, drug interactions and each patient's particular needs into consideration, is essential.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**
None

**Conflict of interest** No conflict of interest

## 4CPS-231 REAL WORLD DATA OF MONOCLONAL ANTIBODIES FOR THE TREATMENT OF HYPERLIPIDAEMIA: ANALYSIS 3 YEARS AFTER INTRODUCTION IN CLINICAL PRACTICE

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**Background and importance** Hyperlipidaemia is the main risk factor for the early manifestations of atherosclerosis and related complications. In recent years, new monoclonal antibodies have become available in clinical practice (evolocumab and alirocumab), termed PCSK9 inhibitors (PCSK9i). Web based monitoring register was used to monitor the access to therapy.
**Aim and objectives** The objectives of the study were to determine the direct healthcare costs in the 3 year period 2017–2019, as well as the incidence of adverse events reported by clinicians related to PCSK-9i therapy at the regional level.
**Material and methods** A retrospective study was conducted. Real data (prescription, dispensed units) were derived from informatics administrative databases. Expenditure incurred for the purchase of pharmacological therapies was instead calculated considering the ex factory price net of the SSN discounts. Adverse reactions (ADRs) were extrapolated from the National Pharmacovigilance Network (RNF) and evaluated using Naranjo's algorithm.
**Results** In 2017, the first year PCSK9i became available, 96 patients were treated (78.5% evolocumab; 21.5% alirocumab) for a total of 587 units dispensed, and expenses were 141 396.34€. In the period under study, there was a growing trend in units dispensed. In 2018, an increase of +429% was seen compared with 2017, probably due to the conclusion of some clinical trials. Evolocumab was preferred to alirocumab (delta 2018–2019=+163.70%). In particular, one of the five local health authorities appeared to have dispensed 46.81% of the total units. Only three ADRs occurred in regional patients. Patients (men:women=2:1), with a mean age of 64.33±15.27 years, had been in treatment for 45 days. 75% of ADRs were attributable to evolocumab. Naranjo's algorithm revealed that 25% of ADRs related to evolocumab were classified as possible and 75% as likely (distributed equally between the two active ingredients).
**Conclusion and relevance** Although the analysis showed an increase in the use of evolocumab, the incidence of use remained too low compared with potential patients eligible for treatment (n=637).[1] The clinical pharmacist, because of his knowledge and skills, is able to take up the challenge that the new paradigm of real world data is posing and generating 'real data for real tests'.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**
1. Nicholls SJ. doi: https://doi.org/10.1007/s11886-019-1103-2.

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## 4CPS-232 USE OF DUPILUMAB IN THE TREATMENT OF ATOPIC DERMATITIS IN REAL CLINICAL PRACTICE

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**Background and importance** Atopic dermatitis (AD) is one of the most common cutaneous inflammatory diseases. Intense itching and rash can significantly compromise the patient's quality of life. Treatment of AD was based on topical/systemic non-specific anti-inflammatories drugs, immunosuppressants or phototherapy. In 2016, the Italian marketing authority (AIFA) approved dupilumab for severe AD treatment. This monoclonal antibody inhibits the signal transduction of interleukin 4 and interleukin 13, implicated in the inflammatory cascade of the pathology.
**Aim and objectives** The purpose of this work was to describe dupilumab's use in real clinical practice and to compare its effectiveness with the marketing authorisation trials.
**Material and methods** The efficacy and safety of dupilumab were evaluated over 52 weeks in a randomised, double blind, placebo controlled clinical trial (LIBERTY_AD_CHRONOS). Disease index for patients enrolled in our structure (January 2019 to June 2020) was recorded in an anonymous database built by matching administrative data and the AIFA monitoring register. The $\chi^2$ test was used to show a statistically significant difference between the clinical trial and real life.
**Results** 166 patients were enrolled during the observed period: median age 43 years (range 25–58), 58% men. At baseline: EASI median value was 28 (range 25–32), NRS was 8 (range 8–9) and DLQI was 21 (range 15–25). After 52 weeks, 60 patients were reassessed. EASI median value was 4 (range 2–7.8), NRS was 2 (range 1–3) and DLQI was 3 (range 2–5). The average percentage reduction in EASI was −81.2% (SD 21.3%), NRS −69.9% (27.0%) and DLQI −15.9% (7.5%). A reduction of 75% in EASI value was recorded for 47 patients (78%).
**Conclusion and relevance** In our structure, 47 (78%) patients had at least a 75% reduction in EASI compared with 58 (65%) in the LIBERTY_AD_CHRONOS study. The average percentage reduction in EASI in our structure was −81.2 ±21.3 compared with −78.4±4.4 in the trial. Although the efficacy data seemed to be different, the $\chi^2$ test showed that there was no statistically significant difference between the trial data and our data (P>0.05). Full compliance with the eligibility criteria, also guaranteed by AIFA's monitoring database, confirmed the efficacy of dupilumab in the real world setting with therapy outcomes similar to the marketing authorisation trial.