

# OFF-LABEL DRUG USE IN ONCO-HAEMATOLOGY SETTING

DI-093

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## INTRODUCTION

Off-label treatments are those that do not correspond to the labelled indications. They are intended to respond to the unmet medical needs of poorly studied populations in clinical trials.

## OBJECTIVE

The aim of this study was to describe the off-label treatments prescribed in the Oncology-Haematology area of a tertiary hospital.

## MATERIAL AND METHODS

Observational retrospective study.  
Off-label drugs prescribed from March 2015 to September 2016.

Data were collected from the pharmacy electronic prescription programme and the multidisciplinary Oncology-Haematology commission database

Demographic

- Age
- Sex

Treatment-related

- Drug involved
- Off-label indication
- Treatment duration
- Economic impact

## RESULTS

- 63 off-label drug uses were approved out of 67 requested.
- 4 (6%) were rejected due to a lack of evidence.
- Oncology was the area with the highest quantity of off-label drug use, 53/67 (79.1%).
- Patients' median age was 55 years (range: 25-85); 27 men (demographic data lacking in 7/63).

Figure 1: Top four off-label drugs prescribed in the Onco-Haematology area

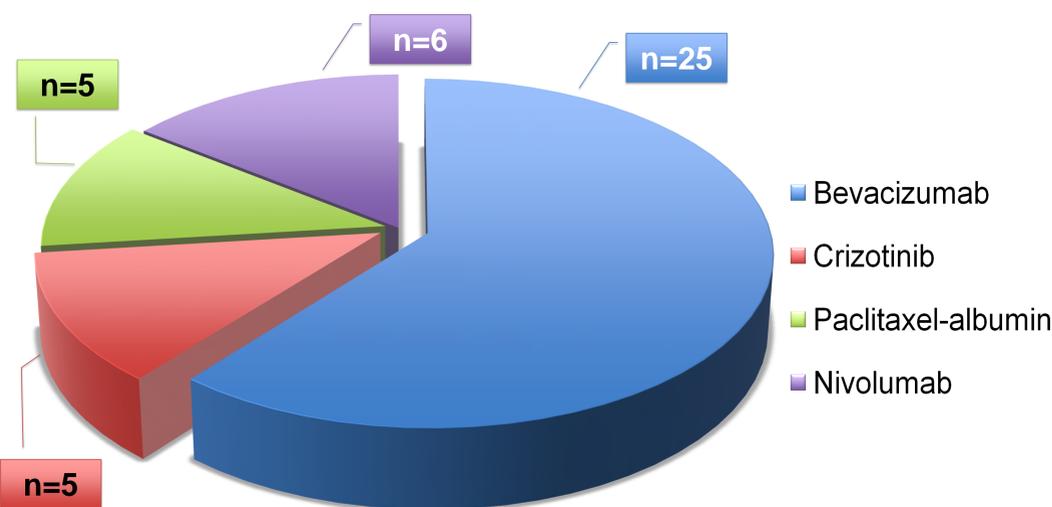


Table 1: Most frequent off-label indications

Drug	n	Indication
Bevacizumab	18/25	Glioblastoma
Crizotinib	3/5	NRAS mutated non-small cell lung cancer
Paclitaxel-albumin	3/5	Neoadjuvant treatment of breast cancer
Nivolumab	2/6	Hodgkin refractory lymphoma

Figure 2: Median duration of off-label treatments

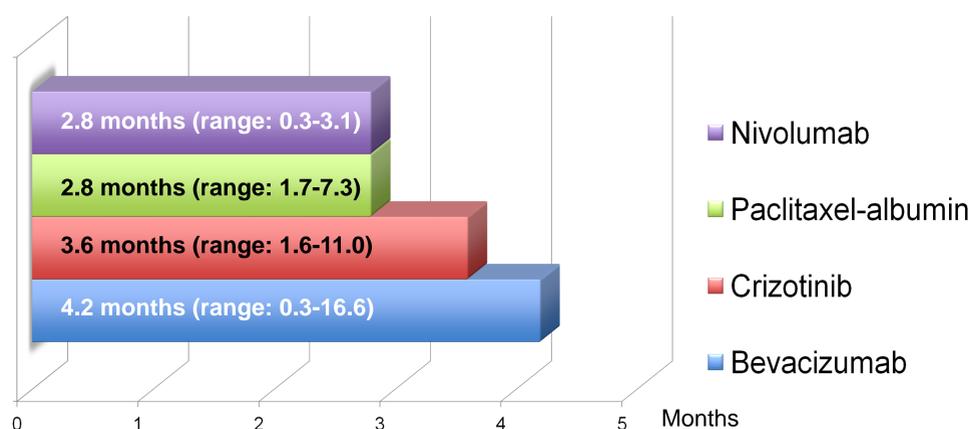


Table 2: Median treatment cost per patient

Drug	Median cost in € (range)
Bevacizumab	18,819.80 (5,790.70 - 72,384.00)
Crizotinib	18,705.60 (9,352.80 - 56,116.80)
Paclitaxel-albumin	3,469.76 (1,301.20 - 4,770.90)
Nivolumab	8,192 (2,048.00 - 12,288.80)

## CONCLUSION

Off-label drug use is a common practice in the Onco-Haematology area. It is crucial to analyze the clinical outcomes of off-label drug use in order to improve decision-making, protocol generation and to estimate the economic impact on our healthcare system.