

# ASSESSMENT OF OVERALL SURVIVAL AND SAFETY IN NEWLY APPROVED ONCOHEMATOLOGIC DRUGS

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## BACKGROUND

To be included on the WHO Model List of Essential Medicines, **cancer drugs should increase OS by at least 4-6 months.**



## AIM AND OBJECTIVES

To evaluate OS benefit and safety of oncohematological drugs approved by the EMA from 2017 to 2020.



## MATERIALS AND METHODS



Retrospective observational study



EMA aprobatons 2017-2020

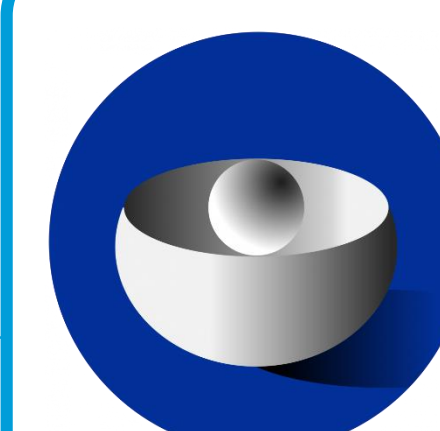
Source of information



European Public Assessment Reports

Variables collected

Primary endpoint, HR of OS with confidence intervals, OS benefit in months and total grade 3 or 4 adverse events

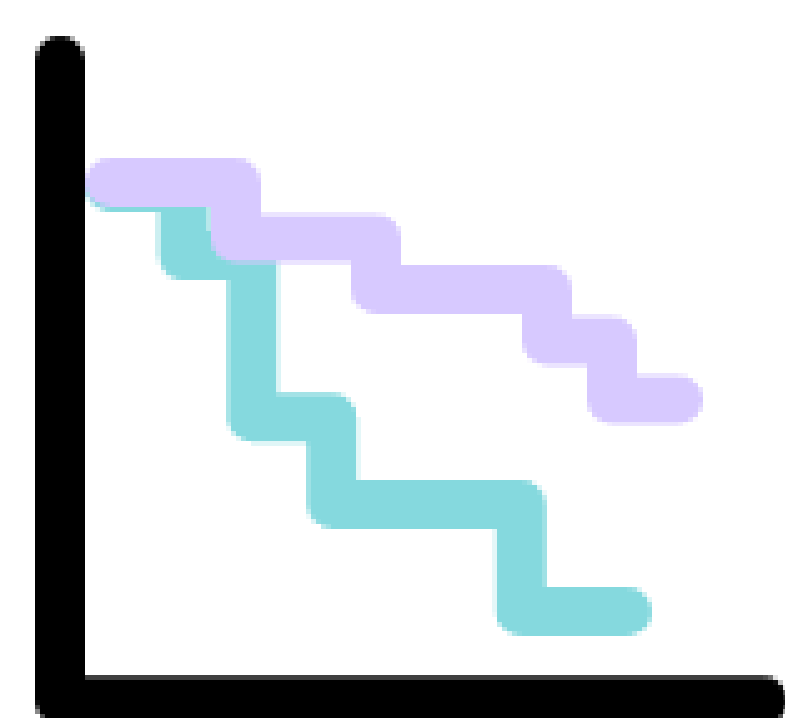


First indication of new oncohematological drugs



Descriptive statistics and Student's t-test to compare ADE.

## RESULTS



4 indications (8.2%) with OS benefit as a secondary endpoint

### OS BENEFIT

49 indications of new drugs

41 (83.7%)  
Surrogate Endpoint

8 (16.3%)  
Overall Survival

Response Rate (20)

Progresión free survival (15)

Disease free survival (2)

Metastasis free survival (2)

Invasive disease free survival (1)

Pharmacokinetic (1)

GLOBAL OVERALL SURVIVAL BENEFIT 12 indications (24,5%)

•8 as primary and 4 as secondary endpoint

•Median not reached in 2 (16.7%)

▪ Median of 4.1 months [IQI 3.6-16.7]

•6 (50%) equal to or exceeding 4 months.



Median HR 0.71 [IQI 0.59-0.77]

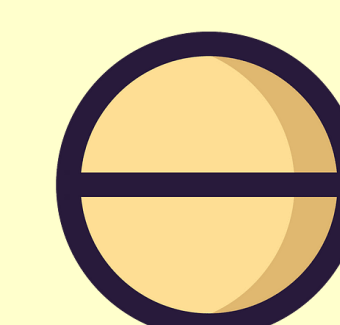
Median Interval Width 0.36 [IQI 0.29-0.42]



### SAFETY

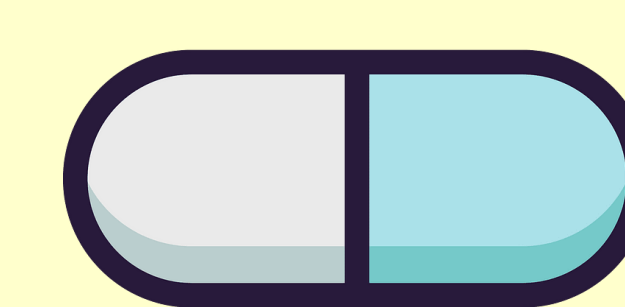
Mean of serious AE

NEW DRUG



63.6%

CONTROL



52.2%

p < 0.05

## CONCLUSIONS

- OS was the primary endpoint in 1 in 6 approved indications. While HR values were acceptable, considerable interval widths were noted.
- Approximately one-quarter of indications demonstrated OS benefit and six approved indications met the lower limit for inclusion in the WHO Model List of Essential Medicines.
- Despite modest OS outcomes, statistically significant increases in AE were observed.

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