

## TITLE

# CLINICAL TRIALS: THERAPEUTIC OPPORTUNITIES, ECONOMIC IMPACT AND SAVINGS FOR THE NATIONAL HEALTH SYSTEM

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## BACKGROUND

AIFA has certified an increase in the number of nationally authorized trials on the European total (17% in 2015, 20% in 2016): research has become an integral part of clinical activity, as well as essential for the Italian health and economic system\*.

## OBJECTIVES

Describe the activities that a dedicated clinical trial pharmacist carries out in the Pharmacy according to Good Clinical Practice: qualitative and quantitative control, traceability, preservation, accountability and preparation of the drugs.

## METHODS

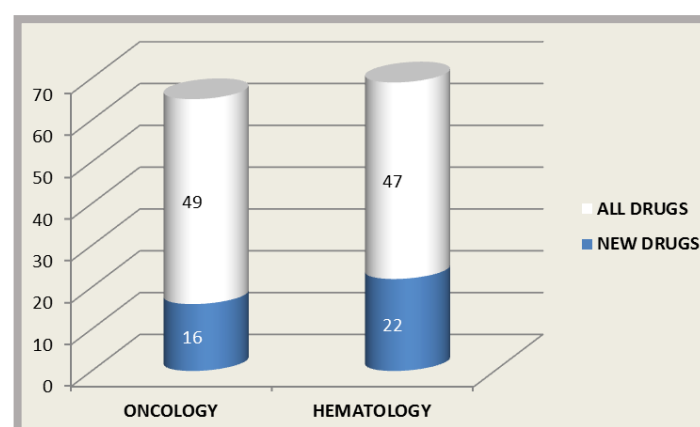
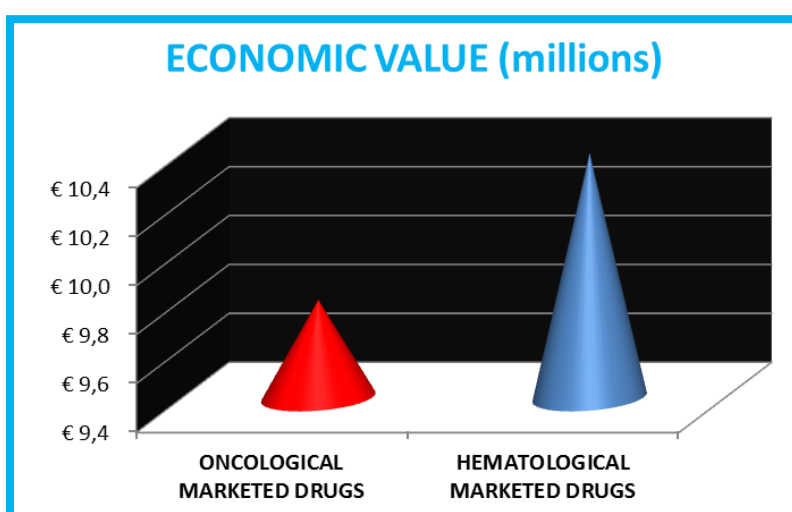
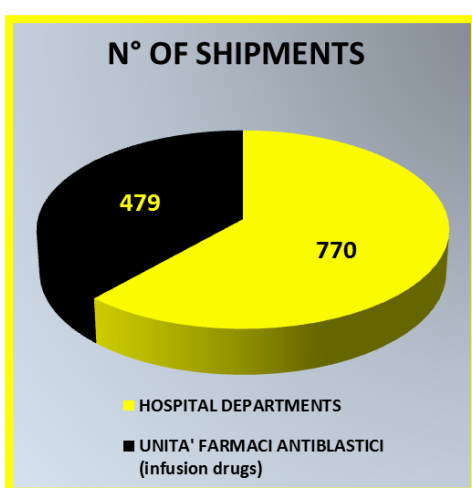
In order to implement the traceability system and to ensure an easier drug accountability, a database that collects all the main information related to the shipments of incoming experimental samples has been created: protocol name and EudraCT, Principal Investigator and destination department, qualitative and quantitative description of the drugs, ID shipment, arrival and check time, transport and storage temperature. The analyzed data has been collected from October 2017 to October 2018: for the clinical trials managed by the oncology and hematology departments has been assigned an economic value (ex-factory price\*\*).

## RESULTS

1249 shipments has been registered in the pharmacy, 771 of which were at controlled temperature: 5 times the datalogger was alarmed and the content has been kept in quarantine until new directives were issued by the clinical research associate; in none of the cases the use of drug has been prevented after the verifications of competence.

The 38.35% of the total shipments were addressed to the Unità Farmaci Antitumorali for the preparation; the shipments of experimental samples dedicated to oncological trials were 522, while 382 to hematological one.

The economic value attributed to the drugs is around € 9.800.000 for oncological drugs and € 10.400.000 for hematological ones. The new molecules (without market price) being tested are 16 for oncology and 22 for hematology.



## CONCLUSION

Onco-hematological drugs are one of the most important items of hospital pharmaceutical expenditure and an important investment by companies. Not all trials will lead to the expected result, however, they can be considered both a new therapeutic opportunity for the patient and a source of savings for the NHS; however, to be verified whether this benefit can be confirmed even in the post-marketing.

## REFERENCES AND ACKNOWLEDGEMENTS

\*[http://www.aifa.gov.it/sites/default/files/Rapporto-OsSC\\_16-2017.pdf](http://www.aifa.gov.it/sites/default/files/Rapporto-OsSC_16-2017.pdf)

\*\*<https://www.codifa.it/>



<http://www.eahp.eu/24-6ER-016>

## KEYWORDS

CLINICAL TRIAL - ECONOMIC IMPACT - COST SAVING

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