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KEYWORDS

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BACKGROUND

Anti-neoplastic and immune-modulatory drugs are on the top of the public pharmaceutical spending. About half of the clinical trials conducted in Italy concern the onco-hematology area, with an important investment by the big pharma and a source of savings for the NHS. According to GCPs and the regulation (EU) N. 536/2014, pharmacists are involved in traceability, storage, return and destruction of investigational medicinal products to ensure the quality of them, the safety of involved subject and the reliability and robustness of data.

AIM

This study aims to quantify the economic value of unused infusion drugs at our center.

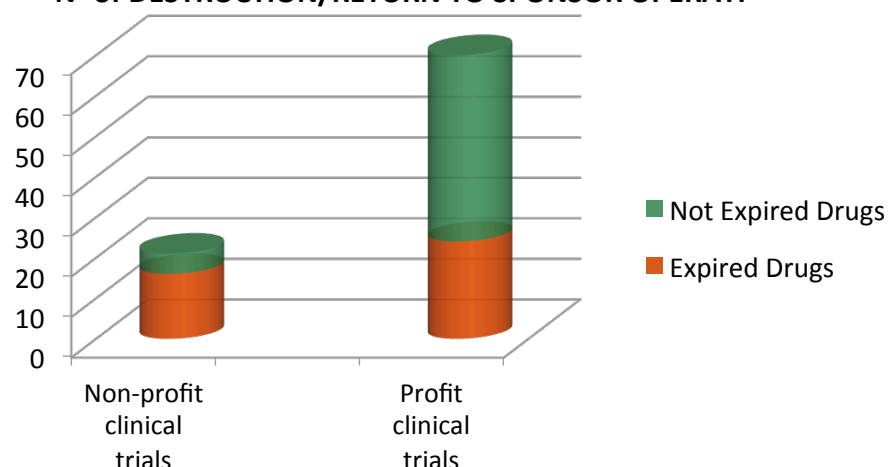
MATERIALS and METHODS

In order to guarantee the traceability system we used a database containing all the main information regarding the drug (product description, batch number, expiry date, location, storage condition) and its accountability (status change date, received, used, available, kit, subject ID, shipment/cycle/returned/destroyed). The analyzed data has been collected from Jan 2018 to Oct 2019 for the clinical trials managed by the oncology and hematology departments. An economic value (ex-factory price) has been assigned to the high-cost drugs destroyed in-site or returned to the sponsor. We considered up to 5 days to the effective expiry date to create a useful range for their potential use.

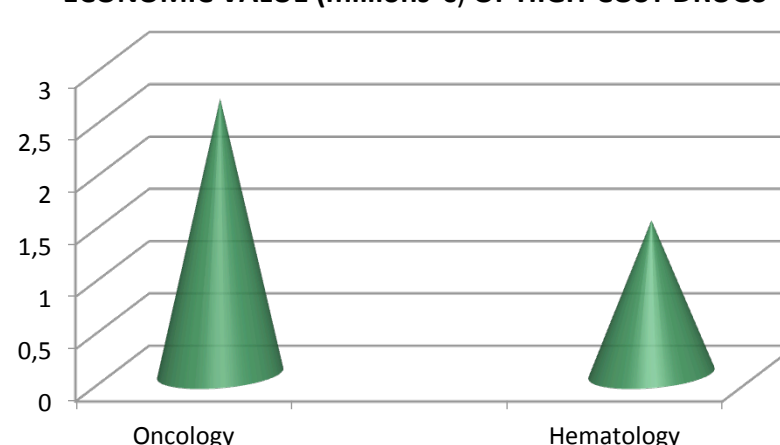
RESULTS

Twenty-six operations of destruction and 69 of return to the sponsor have been carried out on 4 compassionate use programs, 11 non-profit clinical trials and 34 profit clinical trials: in the 55.8% of the cases the drugs were not expired (€ 2.3 million). In 5 cases out of 21 (23.8%) the not expired drugs has been destroyed/returned in non-profit clinical trials while in 46 cases out of 70 (65.7%) in profit ones. The economic value of high-cost drugs on the market is about € 4.1 million (64,2% oncological – 35,8% hematological drugs), which is about 29% of the total annual value of € 14.5 million of infusion drugs managed by our pharmacy.

N° of DESTRUCTION/RETURN TO SPONSOR OPERATI



ECONOMIC VALUE (millions-€) OF HIGH-COST DRUGS



CONCLUSION

Considering the obtained data, improve the drug supply process and a greater collaboration between the involved actors (AIFA-sponsor-clinical trial centers-CRO) is hopeful to reduce the waste described and optimize the available economical resources.

REFERENCES

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