AUXILIARY MEDICINAL PRODUCTS PROVIDED BY SPONSOR OR THE HOSPITAL IN CLINICAL TRIALS (OHP -047)

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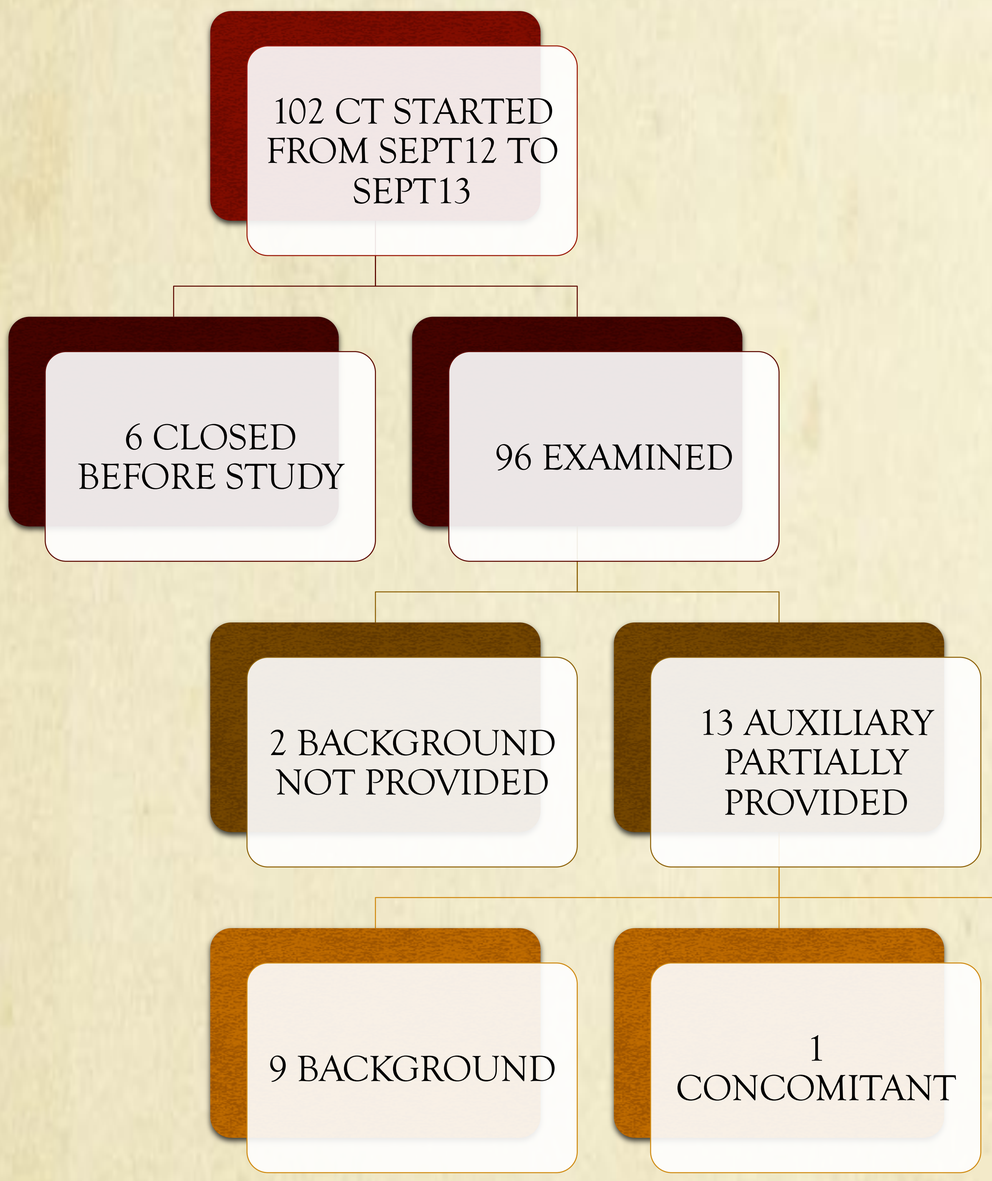
BACKGROUND

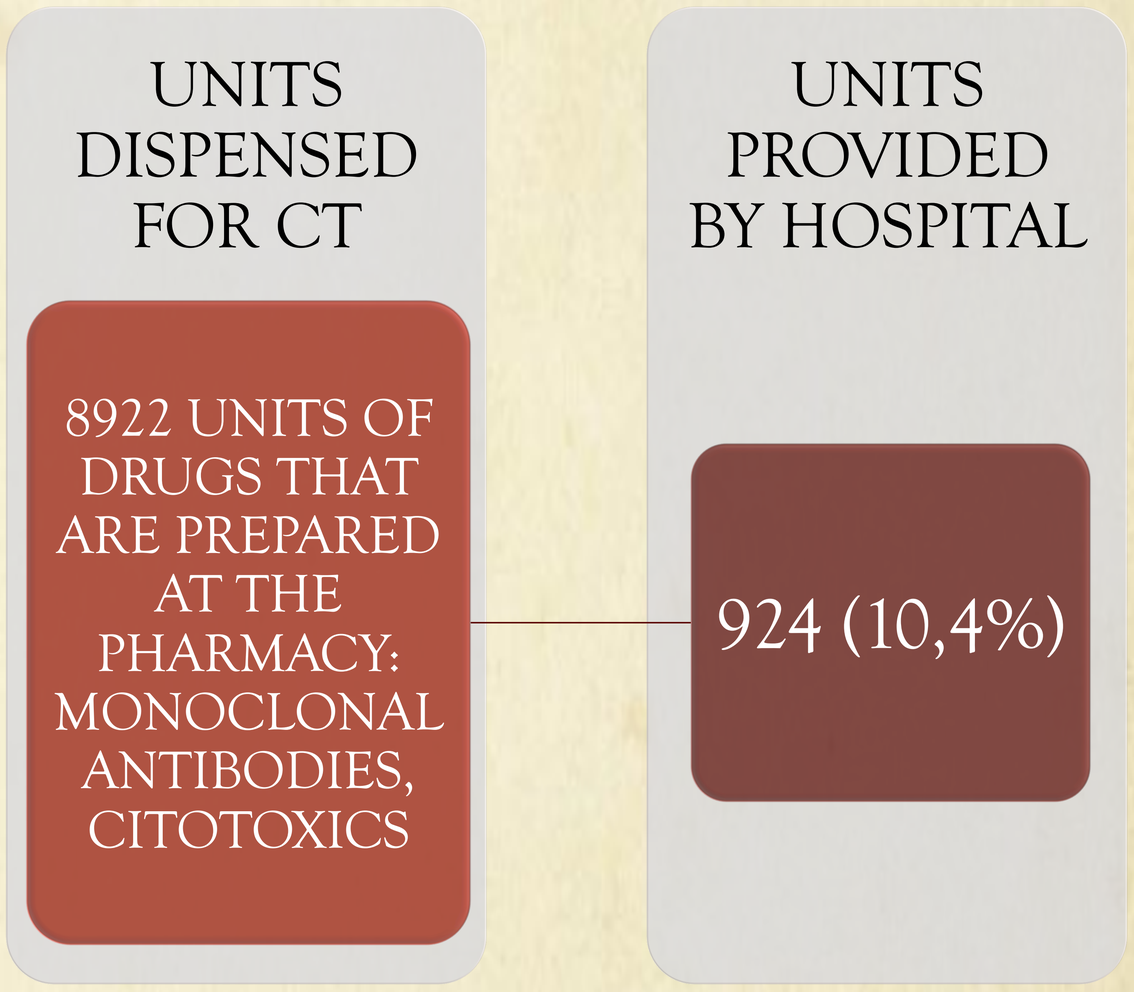
According to current EU regulations, sponsors are free to decide whether or not to provide hospitals with certain medicinal products used in the context of a clinical trial (CT), but not as an investigational medicinal product (IMP), such as background treatment, challenge agents, rescue medication or medicinal products used to assess end-points in the CT. As a result, in some CTs, European hospitals have to pay the costs of these auxiliary medicinal products. The proposal for a new Regulation of the European Parliament and of the Council on CTs on medicinal products for human use will introduce new obligations in respect of manufacturing and labelling of auxiliary medicinal products. The purpose of this study is to asses the number and circumstances of CTs in which sponsors have decided not to provide the hospital with the auxiliary medicinal products and how these circumstances would be affected in the event the proposed new regulation finally comes into force .

MATERIAL & METHODS

Protocols and records of all CTs, which started in our hospital in the period from September 2012 to September 2013, were examined to assess which auxiliary medicinal products were provided by sponsors and which were provided by the hospital.

RESULTS





CONCLUSIONS

Auxiliary medicinal products provided by the hospital were 10,4% of the total amount of units dispensed. If the proposal for a new EU Regulation is finally passed these products should be labelled As a result, either they are labelled in the hospital (which would increase the workload of the hospital pharmacy), or they are labelled and provided by the sponsors (which would reduce the costs of the hospital).