

CLINICAL INVESTIGATIONS ON MEDICAL DEVICES: AN EXAMPLE FROM A LOCAL ETHICAL COMMITTEE

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Background

According to National Legal Framework (D.Lgs 507/92; D.Lgs 46/97), medical devices (MDs), as well as medications, must undergo clinical investigations following strict rules concerning context, ethics, objectives and methods that must have been approved from Local Ethical Committees (ECs). However, only a minority of studies submitted for approval to ECs concerns MDs.

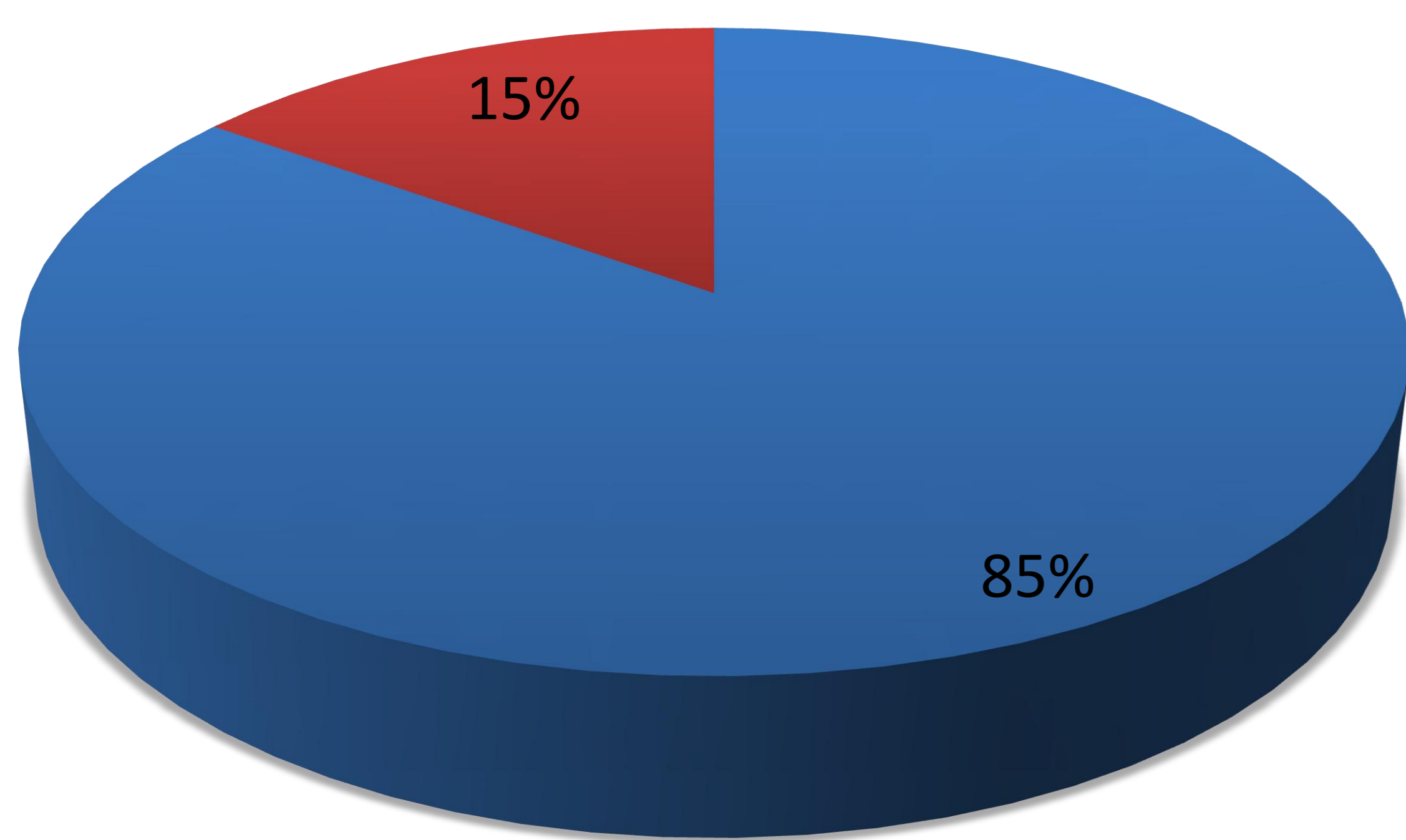


Purpose

The aim of the work was to analyse the number and the characteristics of studies concerning MDs submitted to a Local EC in the two-year period 2015-2016.

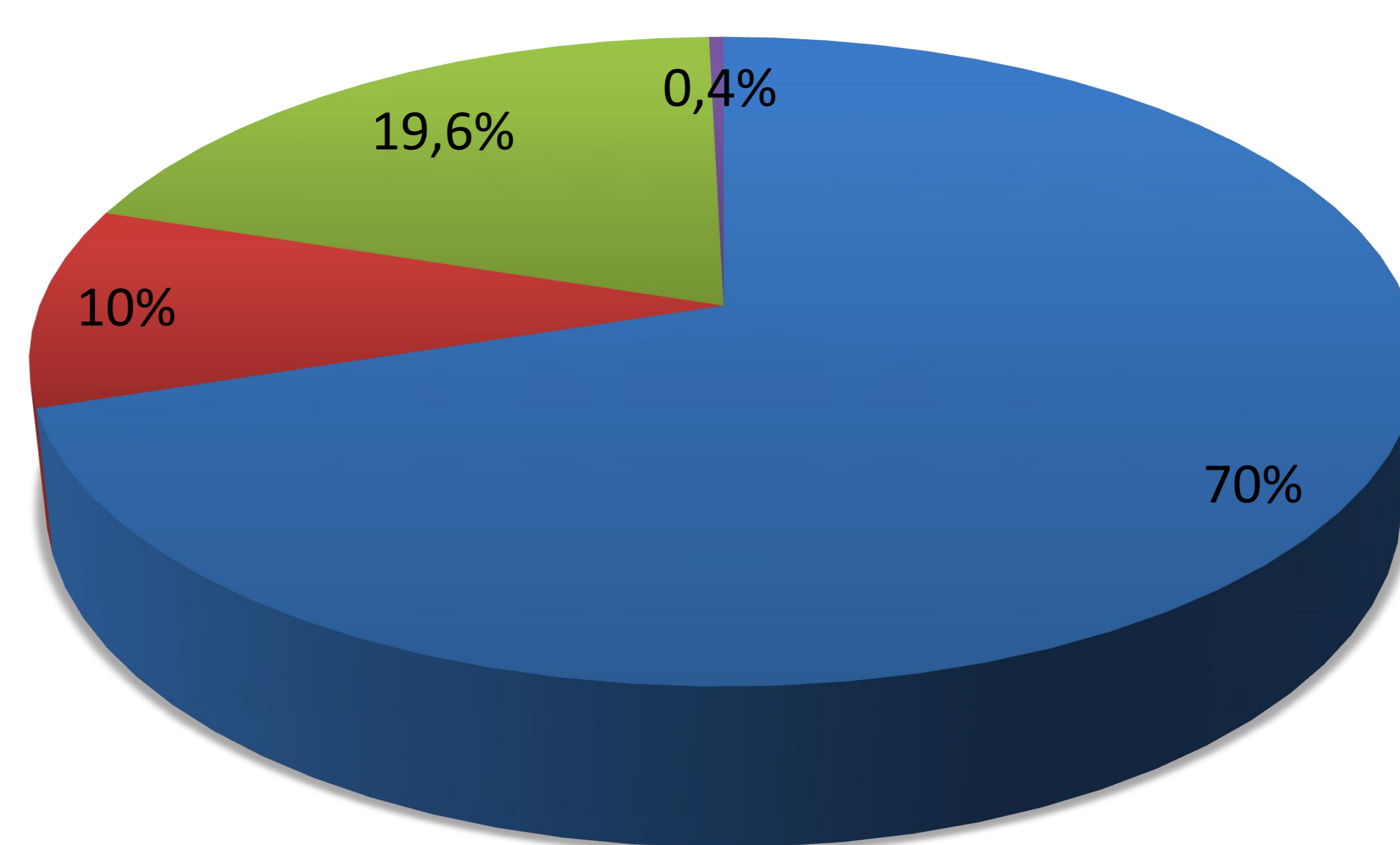
Material and methods

Every study submitted for approval in 2015 and 2016 was derived from the Register of studies of the central Secretariat of our Local EC in order to extract the number of studies concerning MDs and their characteristics. Extracted data from submitted studies concerning MDs were: type of the study (profit/no-profit studies and pre/post-marketing studies), sample size of the study, study population (adults/children), area of interest and type of studied MD.



■ adults ■ children

Figure 1. Study population



■ 10-100 ■ 100-200 ■ 200-1000 ■ >1000

Figure 2. Sample size

Results

Only 20 out of 513 studies presented a MD as the investigational product. Most were no-profit studies (15) and pre-marketing studies (13). Proportion of profit and no-profit studies showed differences between years (no-profit studies were 50% in 2015, 10% in 2016). Sample size involved in investigation was: 10-100 patients (70%), 100-200 patients (10%), 200-1000 patients (19.6%), more than 1000 patients (0.4%). The study population consisted of adults (85%) or children (15%). The major types of studied MDs were: pacemaker, surgical sutures, urogenital and In Vitro Diagnostics (IVD). The major areas of interest were: ophthalmology, neurology, gynaecology, surgery and gastroenterology.

Conclusion

The analysis showed as the incidence of investigations on MDs is very low compared to medications, confirming this area of research as still poorly developed. Although a limited number of data is available, analysed data showed heterogeneity of submitted studies in terms of type, MDs involved and field of investigation. Research on children and young patients is still rare.

