

Pharmacovigilance in the conduct of clinical trials: the experience of an Italian Ethics Committee (EC)

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Background and Objectives

Risk-benefit alerts for investigational medicinal products (**IMP**) received by the Secretariat of the Vasta Romagna EC Area (AVR) and IRST, come from the national and international level, from studies related to the **clinical trials** approved by the EC and AVR IRST, but also from all the trials that investigate IMP around the world.

The significant number of **SUSAR** reports (Suspected Unexpected Serious Adverse Reaction) made it necessary to implement tools to enable these reports to be translated into aggregate information to be disseminated among the stakeholders involved.

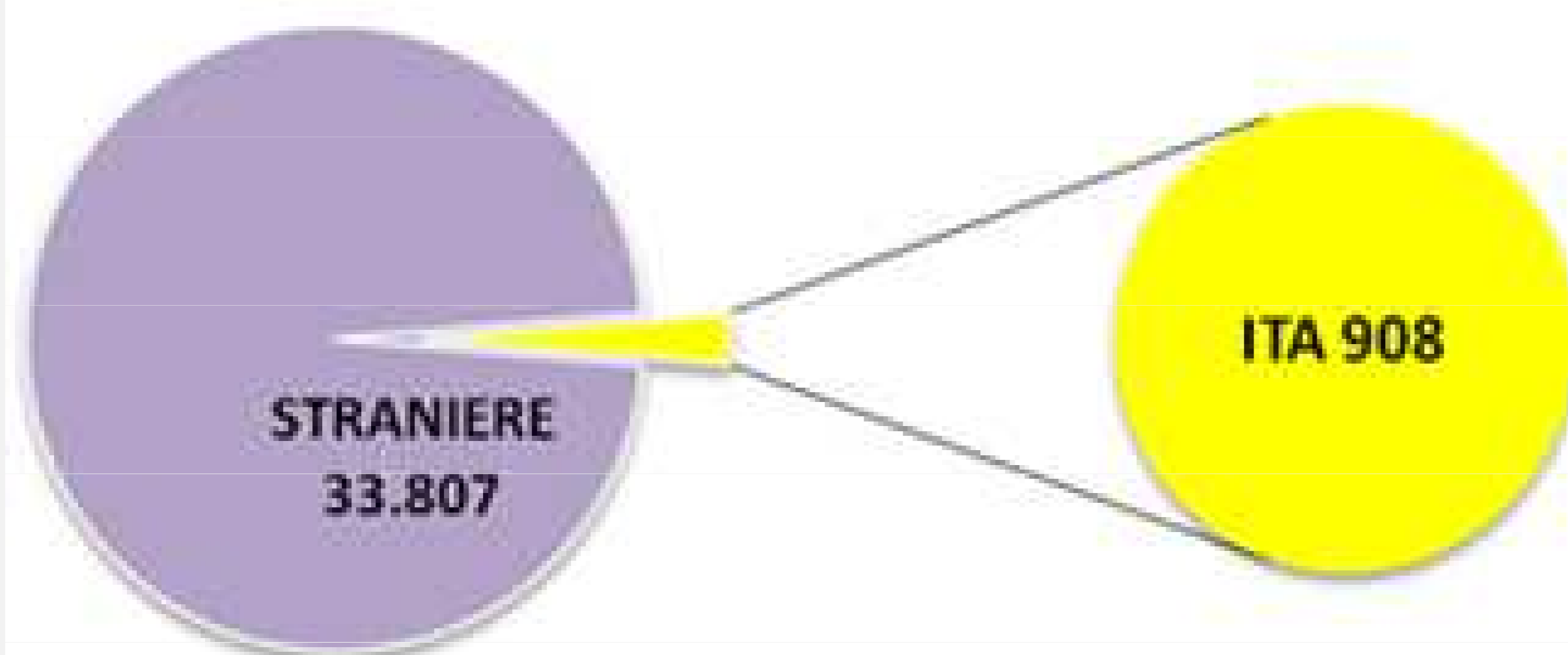
The aim of this study was to find sufficient evidence to assess the **risk-benefit** of IMP, helping ethics committees to manage the numerous problems related to the **pharmacovigilance (PV)** activities.

Materials and Methods

We collected, stored and recorded electronic and printed reports received nationally and internationally during **the 3 years period 2010–2012**. Of these only the national reports were recorded in a **database (DB)** created by the **EC pharmacist**.

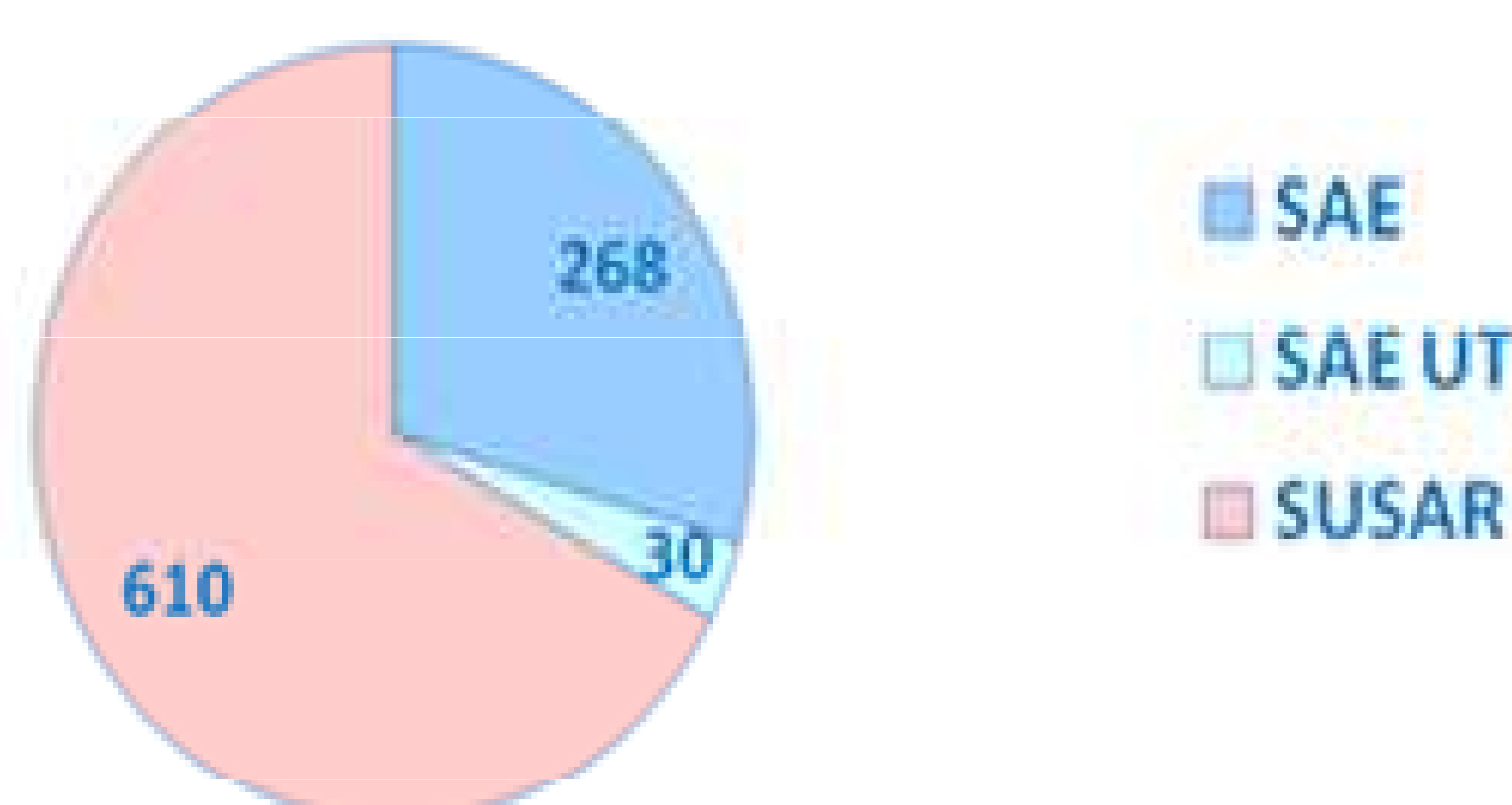
Results

Number of Italian DB recorded alerts in overall incoming reports amount (34.715)

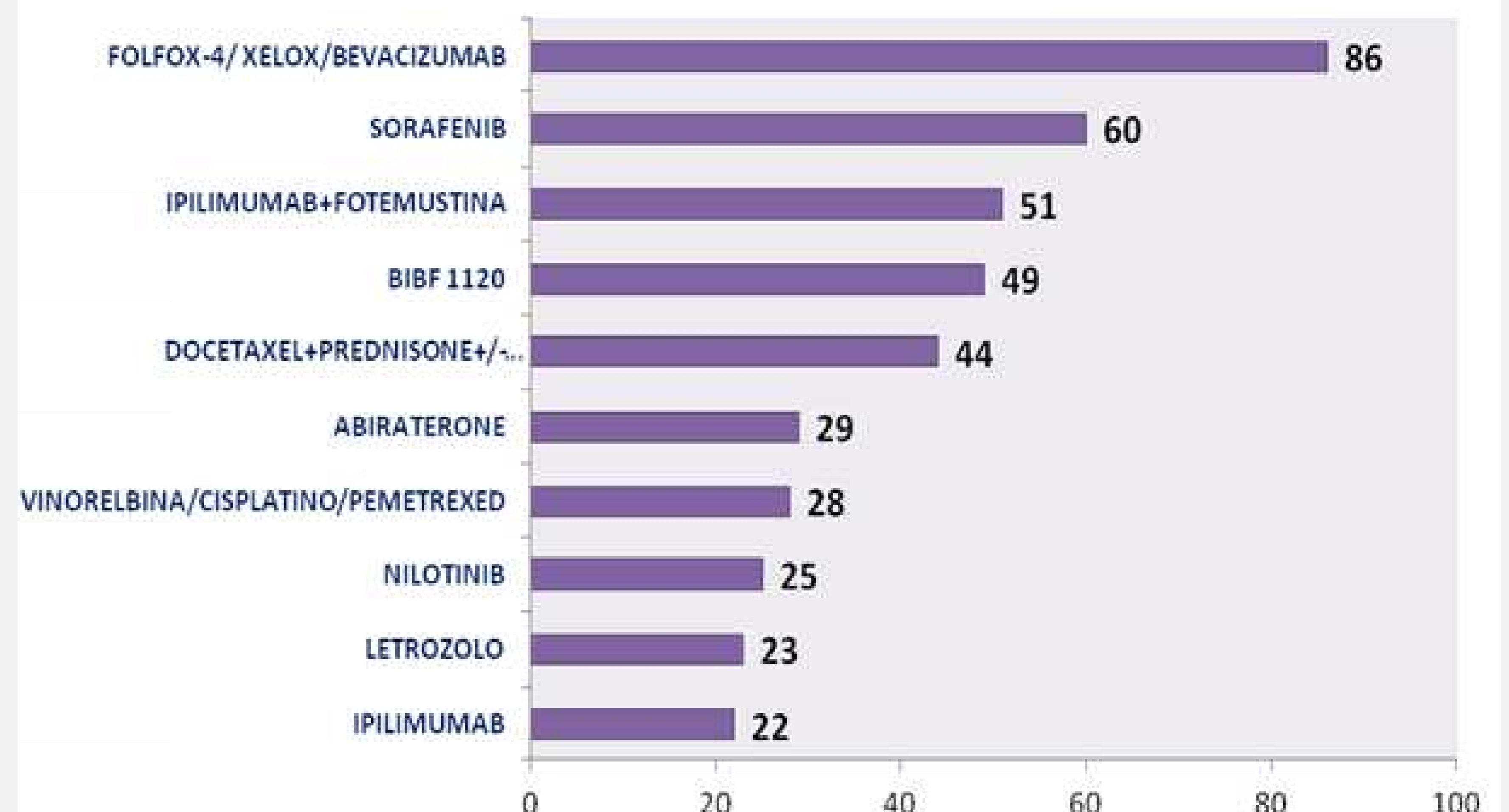


International reports totaled **33,807**, while the national reports (indexed fields in the DB) equaled **908**, related to **207** clinical trials, **37 non-profit** and **170 for-profit** organizations, which added up to **103 IMP**. Furthermore **268** of the 908 Italian reports were **SAE**, **610 SUSARs** and **30 SAE related to compassionate use (UT)**. Gender analysis revealed that 55.3% of patients who had a clinical event were male and 44.3% female, with a mean age of **68 years**. The most used active ingredients for the oncological area (which accounts for **80%** of reports) were: **FOLFOX-4, XELOX - bevacizumab, sorafenib and the association ipilimumab + fotemustine**, in accordance with data gathered in the same period from 'traditional' PV.

Typology of 908 ita-alerts recorded: SAE, SAE UT, SUSAR



IMP top ten (908 total ita-alerts recorded)



Discussion and Conclusions

The descriptive analysis allowed us to categorize all the reports incoming to the EC AVR and IRST secretariat and simulate the possible **economic repercussions to the National Health Service**. The data, in aggregate form, have been **disseminated** to clinicians through internal initiatives and are fundamental to structuring the dialogue and interaction to strengthen the **collegial culture of PV** in the common objective of safeguarding the **welfare of patients**.

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