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

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.

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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