28TH EAHP CONGRESS 20-21-22 MARCH 2024 Bordeaux Sustainable healthcare - Opportunities & strategies ABSTRACTS
AZIENDA OSPEDALIERA OSPEDALI RIUNITI VILLA SOFIA - CERVELLO PALERMO
UNIVERSITÀ DEGLI STUDI DI PALERMO

Contact us: giuliacancellieri.fo@gmail.com

PSQ-13546

DEVELOPMENT OF A NEW METHOD FOR RISK ASSESSMENT RELATED TO MANAGEMENT OF CLINICAL TRIALS IN HOSPITAL PHARMACY

Giulia Cancellieri[1], Piera Polidori[2]

[1] Hospital pharmacy specialization – University of Palermo;

[2] Hospital Pharmacy AOOR «Villa Sofia- Cervello», Palermo (Italy)

What was done?

With the aim of minimizing errors resulting from management of clinical trials in hospital pharmacy, we have developed a method to classify experimental protocols into low-moderate-high risk (risk index - **ρ**). For each of these categories, standard procedures were then outlined in order to minimize the occurrence of any errors.

Why was it done?

Hospital pharmacist provides all management of investigational medical product (IMP), i.e. its conservation, distribution, return and destruction. However, each clinical trial involves different methods of managing the drug: this can mislead the pharmacist who has to manage multiple trials at the same time.

How was it done?

In order to determine risk index (ρ) we have identified all risks related to IMP's management:

- **Pharmacological risk**(φ), dependent on pharmacological characteristics of IMP
- **Technological risk**(α), if drug should be compounding
- **Risk related to number of patients enrolled** (np)
- **Risk inherent to the protocol** (π), i.e. whether protocol involves placebo, or randomization, etc.

These risks were then related through the formula created by us:

$$\rho = \varphi + (\alpha \cdot n_p) + \sum_{i=1}^{8} \pi_i$$

Protocols are defined:

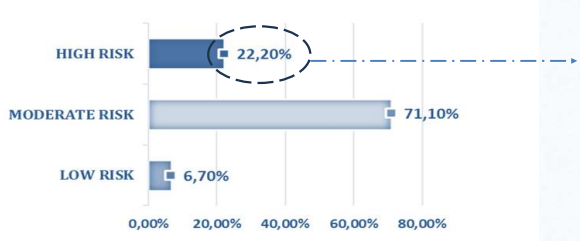
- ❑ **LOW-RISK**, if ρ < 50,
- ❑ **MODERATE-RISK**, if 51 < ρ < 150,
- ❑ **HIGH-RISK**, if ρ > 151

What has been achieved?

We applied this method to 45 active trials in our hospital.

By applying aforementioned formula, we found that (*Graph 1*):

Graph 1. Risk index - ρ



For these, standard procedures were applied, to improve the safety of patients enrolled in a clinical trial.

What next?

We promote use of this method in other clinical centers, because we believe it can be a valid tool for risk minimization.

Finally, we hope that we will receive numerous feedback from these centers to further improve the proposed method.