HOSPITAL PHARMACY CONTRIBUTION TO CLINICAL TRIALS: TYPIFICATION OF MEDICATION INCIDENTS AND PHARMACEUTICAL INTERVENTIONS IN A CLINICAL TRIAL UNIT

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1 WHAT WAS DONE?

A database to notify **medication incidents (MI)** and **pharmaceutical interventions (PI)** in the Clinical Trials Unit was developed in the Pharmacy Service of a tertiary hospital.

2 WHY WAS IT DONE?

- Classical methods for reporting MI do not allow for a correct classification in the field of **clinical trials**.
- A **clinical tool to notify MI and PI** was implemented with the following objectives:
  - To unify their **classification criteria.**
  - To gather complete **information** for analysis.
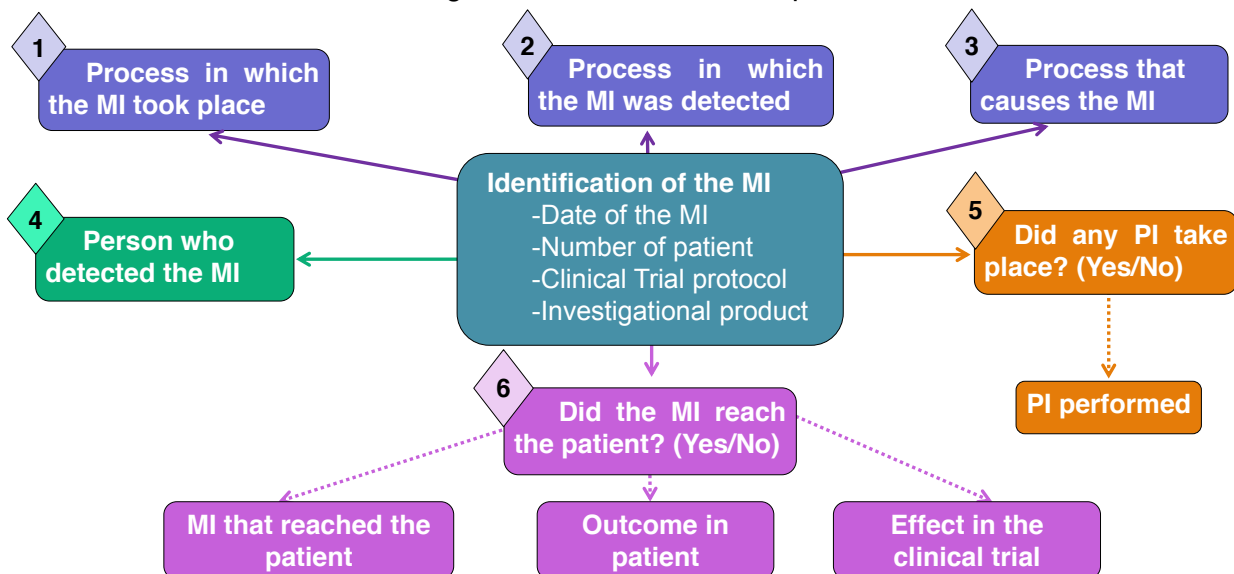 - To implement **improvement measures**.

3 HOW WAS IT DONE?

- All the processes involving drugs in clinical trials were evaluated by a **Failure Mode and Effects Analysis** (FMEA).
- For each process, the possible incidents and their resulting effects on the patient were recorded.
- A database was designed in Microsoft® Access with defined lists of choices to allow pharmacists **notify both MI and PI** that occur in the Clinical Trials Unit.

4 WHAT HAS BEEN ACHIEVED?

A database with the following information has been implemented:

5 WHAT NEXT?

- The implemented notification system will be further **expanded and adapted** over time.
- Future aim is to analyse MI for establishing **improvement measures** and checking their results.

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