











# 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.

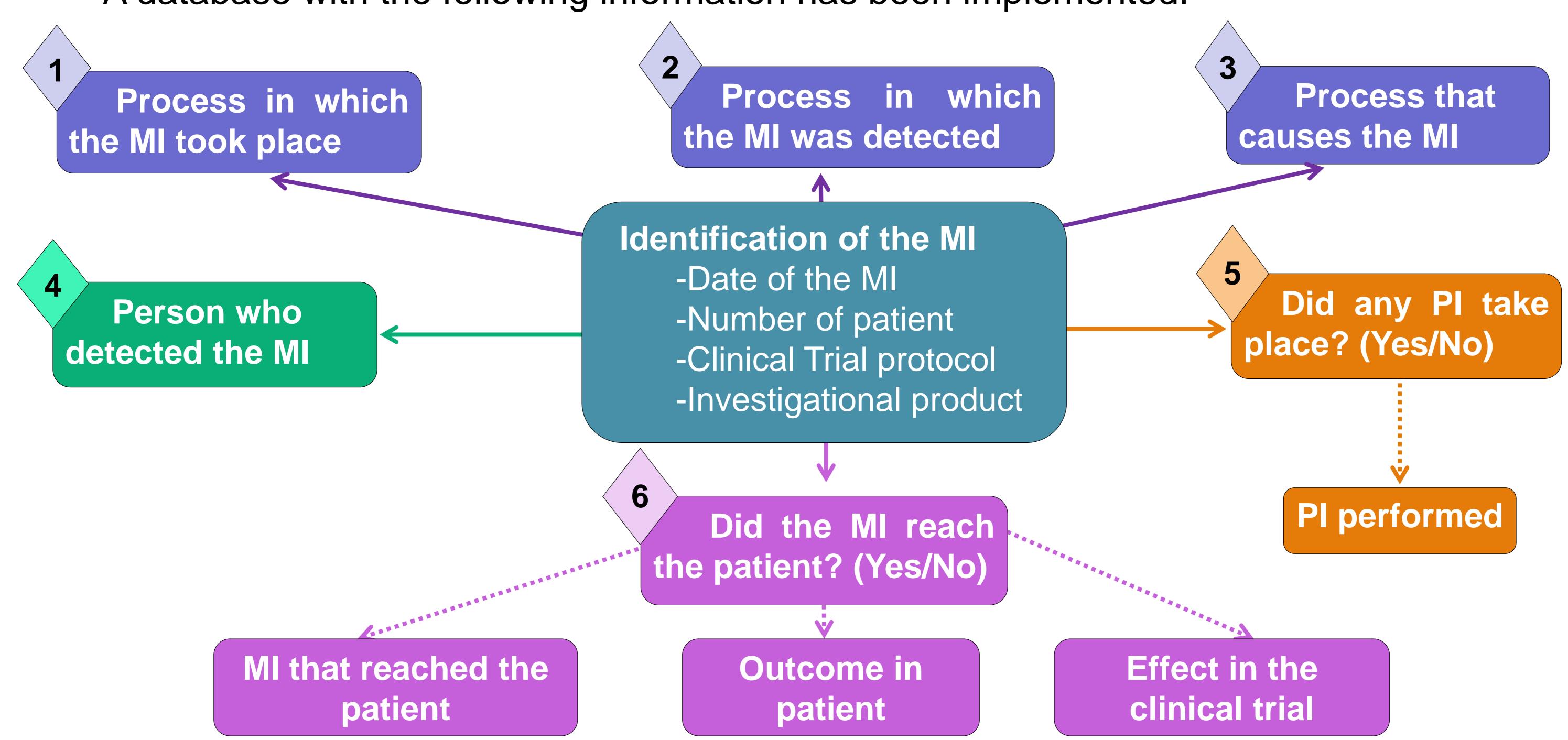
### HOW WAS IT DONE?

- 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.



#### 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.

