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:

1. Process in which the MI took place
2. Process in which the MI was detected
3. Process that causes the MI
4. Person who detected the MI
5. Did any PI take place? (Yes/No)
6. Did the MI reach the patient? (Yes/No)
7. MI that reached the patient
8. Outcome in patient
9. Effect in the clinical trial
10. Did PI perform?

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.