

# OPTIMISATION OF THE SETTING-UP OF DATA SAFETY MONITORING BOARDS IN CLINICAL TRIALS : LESSONS OF A SIX YEARS ANALYSIS.



With the support of the « Association des Internes et des Anciens Internes en Pharmacie des Hôpitaux de Lyon »

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## BACKGROUND

In order to monitor the safety of patient in clinical trial, Data Safety Monitoring Boards (DSMB) are organised. These DSMB contain independent volunteer experts of medical field of the research (clinicians, pharmacologist, methodologist or statistician). They give their advice about the continuation with or without modification or the stop of study. They are more and more asked by competent authorities during the submission of initial study authorisation. This is an ambitious challenge to improve the organisation of these DSMB which requires time and work. Few studies were conducted on this topic.

## OBJECTIVES

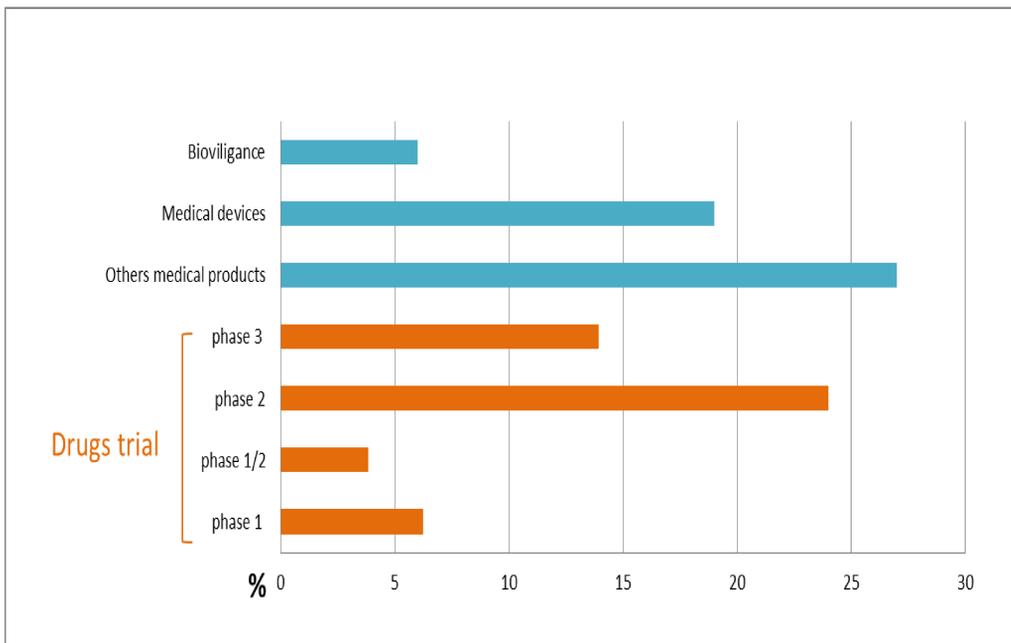
1-Identify which studies need a DSMB 2-Demonstrate the benefit of initials meetings

## METHODS

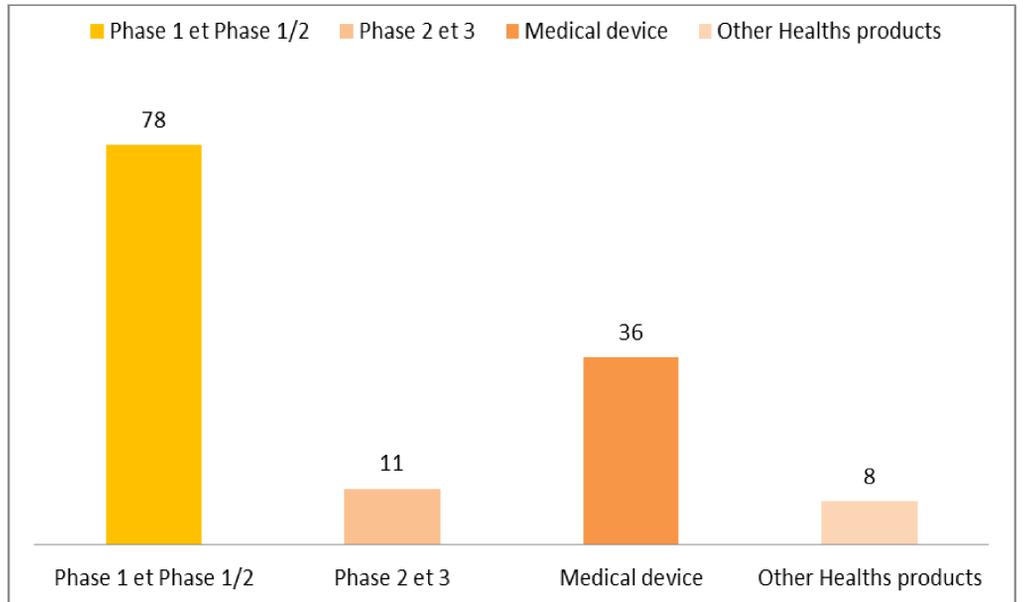
The study design is observational retrospective, based on a register of an academic sponsor. Data from August 2011 until September 2017 on 89 clinical trials (investigational medical products, medical devices, other health products, biovigilance) with DSMB were extracted. The following parameters were analysed : types of study, meetings before patient inclusion, meetings during studies and actions taken by the sponsor following the decisions of the DSMB. The need to establish DSMB meeting was measured by the decision of experts for all types of studies. The hypothesis that an initial meeting before the start of trials may lead to more relevant DSMB recommendations was tested by a Khi-2 test.. There can be no stop on the initial meeting.

## RESULTS

### 1- Distribution of study with DSMB (%;n=89)



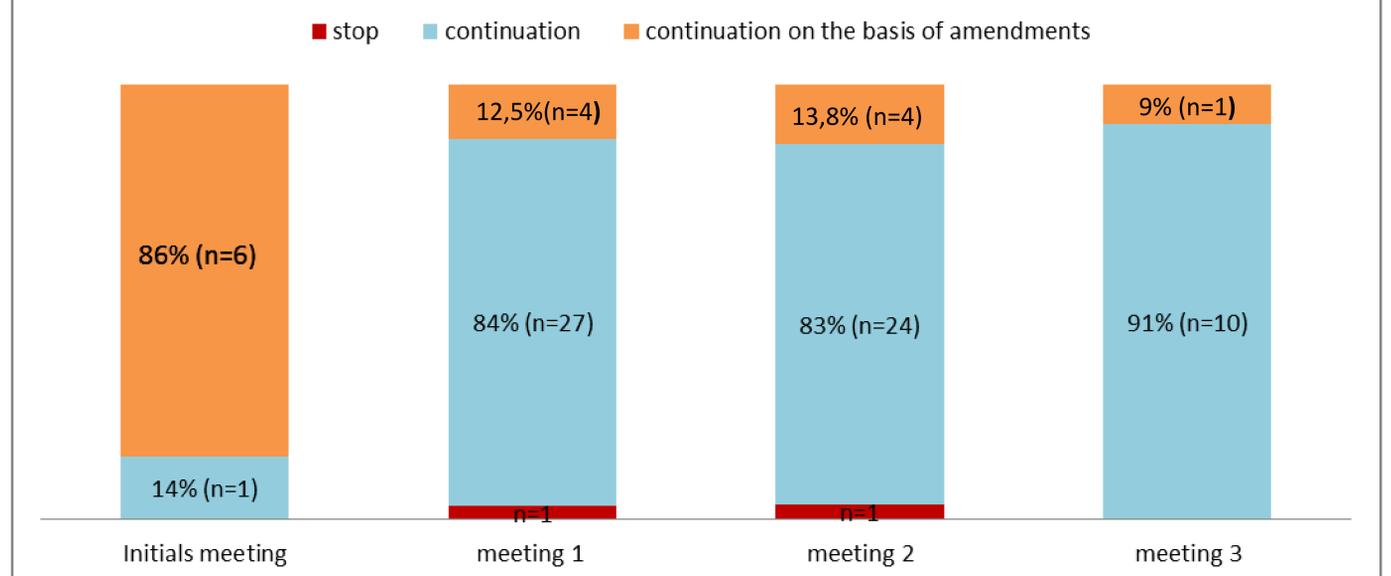
### 2-Distribution of DSMB recommendations to modify or stop the trial depending on the type of study (%)



### 3- Benefit of initials meetings

Establishment of initial meeting has highlighted more recommendations by DSMB members (86%; n=6) compared to other studies without initial meeting (12,5%;n=9) (p-value <0, 0001). The graph on the right shows the number of continuation without modification, continuation on the basis of amendments or stop depending on the chronology of the DSMB meeting.

### Initials meeting highlights recommendations by DSMB



## DISCUSSION- CONCLUSION

The major importance of DSMB decisions were for the early drugs phase trials and medical device studies. The setting of a DSMB should be highly recommended for these studies types. The initial meetings before the start of the study is one of the main key of this challenge to ensure a good safety monitoring. A national survey is needed in order to validate our results and make recommendations.