

Introduction & objective

↗ Clinical trials with **preparation of investigational medical product** + ↗ protocol requirements → ↘ adaptability of clinical trial sites → ⚠ **Recurring disagreements** during site initiation visits

Issue : Protocol requirements may be difficult to reconcile with actual preparation conditions, which often lack scientific justification, leading to a perception that **pharmaceutical expertise is not fully recognized**.



➡ **Objectively assess the disagreements arising during implementation and evaluate any associated potential risks**

Materials & methods

Identify



- All disagreements occurring during SIVs
- Period : November 2022 → December 2024

Describe



- For each disagreement, collection of :
- **Clinical trials characteristics** (phase, type of sponsor, category of preparation)
 - **The nature of the disagreement**
 - **The pharmaceutical solutions proposed**
 - **Sponsor's response**

Constitute



- Constitution of the **expert panel**
- Selection based on comparable professional profiles (number of studies, type of preparation) and strong national representation

Scenario design



- Selection of **representative scenarios**
- Formal description of each case

Assess



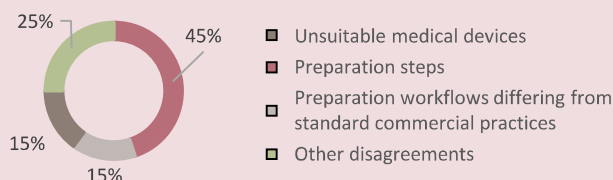
- Identification and consensus-based assessment of risks according to a predefined grid :
- **Organizational**
 - **Operator-related**
 - **Patient-related**

Results

Frequent disagreements

- **35/67 SIVs with ≥ 1 disagreement, or 52% of SIVs**
- **53 disagreements in total**

The nature of the disagreement



Characteristics of studies with disagreements

Phase of the study	
Phase 1	17%
Phase ½	6%
Phase 2	33%
Phase 3	44%

Category of preparation	
Chemotherapy	64%
Compounding	31%
MTI	6%

Type of sponsor	
Industrial	86%
Academic	14%

Most pharmaceutical proposals were rejected

29 disagreements deemed significant and led to a proposed adjustment → **17 rejections**
Of the 17 rejections → 60% without scientific justification



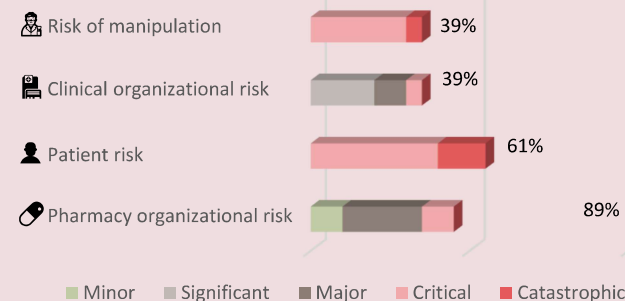
● Suspension of 3 studies

What risks behind these disagreements ?

Analysis of **18 scenarios** by **19 expert pharmacists** at national level



Assessment of potential risks



Discussion & conclusion

This study highlights the **high frequency of unresolved conflicts** between pharmacists and sponsors during SIVs involving IMP preparation, with most **proposed adjustments being rejected**. These disagreements, beyond organizational constraints, pose **significant risks to both patients and staff**. This study also demonstrates that certain protocol requirements may, paradoxically, **compromise the safety and feasibility of IMP preparation**. Strict adherence to the protocol can thus lead to the identification of **major to critical risks**, sometimes leaving **study suspension as the only recourse**.

Early integration of pharmaceutical expertise is essential to ensure the **safety and feasibility** of clinical trials.