

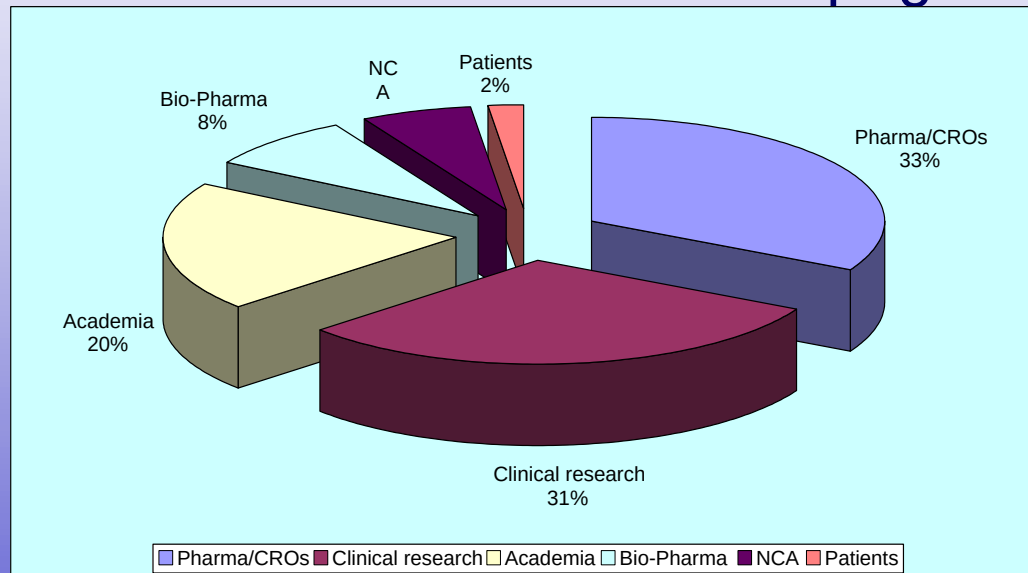
# **Workshop on the guideline for First-in-Man Clinical trials for potential high-risk medicinal products**

## **Overview of comments Highlights**

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# Introduction

- High interest
- 57 organisations commented - 200 pages of comments!



- All comments will be answered in the published overview together with the final guideline

## ***On the positive side***

- The guideline is clearly written and gives a brilliant overview of a complex issue
- FIM guideline is important in establishing a clear efficient process for both applicants and regulatory agencies
- This guideline provides a detailed and structured overview of the many factors that need to be considered before initiating a first-in-man clinical trial in healthy volunteers with a potential high-risk investigational medicinal product

# General comments

## *Overall guideline*

- The guideline is too general
- Clear examples would prevent checklist approach
- Recommendations given in the guideline already exist in other guidelines



## ***High-risk Medicinal Products***

- Definition is too vague
- Definition should be aligned with the “Duff” report “higher-risk” agents
- Design of Phase I clinical trials can be the risk
- Avoid the “stamp” high-risk
- The title should reflect the general applicability of the guideline



## Comments on requirements

- Large battery of additional studies required for high risk products
- Antibodies would require more specific consideration



- Concentration –response analysis should not be mandatory
- Could be interpreted as a check-list approach

- Focus on risk mitigation strategies through the integrated analysis of all pre-clinical data and appropriate design of clinical trials

## Consequences

If the definition of **High-risk Medicinal Products** is taken too widely, it could have detrimental effects on innovation



## ***Suggestions for the future***

- Dedicated National Committee to review these specific CTA
- A European Steering Committee could monitor and ensure harmonised application of the guideline

