CHMP draft Guideline on requirements for first-in-man clinical trials for potential high-risk medicinal products

Bioindustry Perspective

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Comments on draft guideline

- We support the development of the CHMP guideline
- There should be clear differentiation between chemical drugs and biologicals
- Not every new monoclonal antibody is a high-risk medicinal product
- Differentiation between different types of MAbs – antagonists versus agonists

Comments on draft guideline (continued)

- Manufacturing perspective:
  - Quality requirements should be based on stage of development
  - Otherwise, significant costs and delays will result if there are increased expectations regarding product characterisation
- More detailed guidance should be provided on the calculation of the first dose in man and subsequent dose escalation
- Clarification regarding the use of an independent drug safety monitoring board

Scope of the guideline

- The draft guideline is too general
- The scope of this guideline should be re-considered
- There are two possibilities:
  - First, the guideline covers all first-in-man studies and should focus on risk mitigation strategies
  - Second, the guideline covers only first-in-man studies for high risk products. In this case, we need to define what "high risk" is?

Definition of potential high-risk IMP

- ANY first in class compound could be caught in this definition
- If the definition of high-risk products is applied too widely this could have a detrimental effect on innovation
- We recommend that the definition of “high-risk medicinal product” is based on well defined criteria

In summary

The first-in-man clinical trials guideline will help to establish clear expectations of the data requirements for both applicants and regulatory agencies