

Recap: Track B Applying Risk Management, Risk Assessment and Design Space to OINDP Regulation

General Observations

- Wide diversity of experience/knowledge
- Lack of practical experiences with respect to the questions posed
- Concerns regarding accessibility to regulatory authorities as we enter the new paradigm
- Difficulty moving away from historical approaches
 - Lack of clarity with respect to benefits of new approaches
 - Lack of experience demonstrating benefits of new paradigm

Questions Regarding Risk Assessment and Risk Management

- How can sponsors encourage the use of risk analysis early and throughout the design and development process, as a guide to the process?
- What is the role of risk assessment in defining the Design Space for OINDP?
- How are risk management tools applied during development and what tools are suitable for each stage?
- How can risk assessments be communicated in regulatory submissions?

Risk Assessment & Risk Management

- Significant number of people are using available tools (*e.g.*, FMEA) and see how the tools can assist in identifying critical factors, but the tools, as of yet, are not being used to define Design Space
- Some are using Risk Assessment to identify major factors that are studied further in a design of experiments
- People generally see that Risk Management can be a tool in establishment of Design Space

Questions Regarding Design Space

- How can design space be linked /correlated with the clinical program?
 - Through specific clinical trials?
 - Comparison on the design space with in vivo results?
 - Comparison with in vitro surrogates?
- How can the design space be established in parallel with the clinical program?
- What is the best process for obtaining regulatory buy-in to the design space and risk management program?
 - Through pre-IND meeting or end of phase II meetings?
 - Through a special protocol assessment?
 - Through some other new type of meeting?

Design Space (II)

- People could see the options of linking DS to clinical program, and could see some are more attractive than others but significant concerns remain
- Concerns include:
 - Cost
 - Time
 - Ethical
 - Relevance: some remain unconvinced that the result will tell what you seek to establish

Design Space (II)

- People don't know yet how best to approach regulatory authorities regarding presentation of design space for OINDPS
- People interested in how the FDA Pilot Programs conclude and the lessons learned so they can be applied to OINDP

Thank You