Clinical Evidence Requirements

Panel Discussion: Regulator, Notified Body & Industry

Moderator: Larry Kessler

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General Overview

- **What guidelines/recommendations shape a good clinical trial**
  - What is considered Good Clinical Practices
- **What is considered sufficient Evidence from reviewer perspective (mention EBM)**
  - Review process & assessment at the agency based on classification of product

Notified Body Perspectives

- Challenges & Issues in new PAL focusing on clinical evidence requirements
- Clinical Requirements in EU – Notified Body perspective

Regulatory Perspectives

- Provide general overview of SG5 guidance docs and recommendations

Industry Perspectives

- Determining clinical evidence requirements for product registration
- Applying international standards & guidelines on clinical trial eg. Good Clinical Practice (GCP)