Patient-Centric Specifications Panel Session
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Patient-Centric Drug Product Quality Specifications: A Convergence of Clinical and Nonclinical Considerations

Organized by Stan Altan (Janssen) and Tim Schofield (CMC Sciences)

Abstract

The notion of "patient centric specifications" has received increasing attention over the past few years, following the passage of the Cares Act in 2016 by the US Congress. This act was intended to accelerate the development of modern medicines, with a patient focused view. Various guidances have been issued in connection with the act, mainly in the clinical space. The nonclinical quality implications have also been evolving in parallel with the clinical developments, where the term “patient-centric specifications” has become more widely used. This term has supplanted to some extent the earlier term, “clinically relevant specifications”. This panel session will review the emergence of these terms, and how it is currently impacting drug development. A major objective of the session is to explore the relevance of patient centricity to the development and implementation of CMC acceptance criteria and propose a framework for understanding of the concept from a holistic perspective.

Panelists :

- Hans Coppenolle (Janssen)
- Trine Kvist (Novo-Nordisk)
- Katharina Reckermann (Roche)
- Sandra Suarez Sharp (Simulations Plus, formerly FDA)
- Stan Altan (Janssen), moderator and discussant