

Developing pharmacological treatments for the rapid reduction of suicidal ideation in depression

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Interest

Name of organisation

Grants

Honoraria

Shares

Johnson & Johnson

Paid positions

Senior Director, Janssen Research & Development, LLC

Advisory boards

Other involvement

Session Rationale

- New class of rapidly acting antidepressants has given rise to the interest in the development of pharmacological treatments targeting suicidal ideation (SI)
 - Distinct from the development of treatment to prevent or reduce risk of suicide
- Patients with active suicidal ideation and intent have typically been excluded from clinical trials of antidepressants
- At least 3 pharmaceutical companies and numerous academic investigators have conducted clinical trials with this objective
- Much has been learned about the operational aspects, methodological challenges and regulatory considerations of this novel treatment indication for a vulnerable patient population with high unmet medical need

Questions

- Is the rapid reduction of SI clinically meaningful?
- What are the methodological challenges in evaluating treatment differences in SI?
- What have we learned from the implementation of clinical trials in this population?
- How can we enrich populations and enhance signal detect through the use of biomarkers, digital technology and predictive algorithms?
- How can real-world study designs help to establish the clinical meaningfulness of SI reduction and overcome some of the methodological challenges encountered in RCTs?

Commentary

- US Regulatory Perspective
- EU Payor Perspective