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

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Carla Canuso, MD
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