

Should Patients with Any Degree of Suicidal Ideation and Behavior be Included in Clinical Trials?

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- International Study of Clozapine in Suicidal Patients¹ (InterSePT) (N=980)
 - Prevention study with time-to-event outcome
 - Active comparator
- Numerous studies of non-pharmacological interventions in suicidal subjects

- FDA Draft Guidance June 2018: “Patients with a history of suicidal ideation and behavior need not be systematically excluded from trials ... Sponsors should provide the rationale for restrictive inclusion and exclusion criteria”.
- 3 compounds currently in development for the treatment of depression and SIB

- SI/B as a symptom of disease under study vs. SI/B as a target of treatment
- SI/B reduction vs. prevention of suicide
- Trans-diagnostic vs. disease specific

- Not a debate of YES or NO
 - Rather, a discussion of HOW and WHEN
- Regulatory Questions / Commentary
- Study Design Implications
- Practical Recommendations