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Titel des Beitrags:
Issues and perspectives in designing clinical trials for negative symptoms in schizophrenia.

Abstract:
A number of pharmacological agents for treating negative symptoms in schizophrenia are currently in development. Unresolved questions regarding the design of clinical trials in this area were discussed at an international meeting in Florence, Italy in April 2012. Participants included representatives from academia, the pharmaceutical industry, and the European Medicines Agency (EMA). Prior to the meeting, participants submitted key questions for debate and discussion. Responses to the questions guided the discussion during the meeting. The group reached agreement on a number of issues: (1) study subjects should be under the age of 65; (2) subjects should be excluded for symptoms of depression that do not overlap with negative symptoms; (3) functional measures should not be required as a co-primary in negative symptom trials; (4) information from informants should be included for ratings when available; (5) Phase 2 negative symptom trials should be 12 weeks and 26 weeks is preferred for Phase 3 trials; (6) prior to entry into a negative symptom study,
subjects should demonstrate clinical stability for a period of 4 to 6 months by collection of retrospective information; and (7) prior to entry, the stability of negative and positive symptoms should be confirmed prospectively for four weeks or longer. The participants could not reach agreement on whether predominant or prominent negative symptoms should be required for study subjects.

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