

Proposal for a Database for the Evaluation of the Potential Risk Factors for Suicidal Acts During Index Acute Treatment Episodes with Pharmacotherapies

Does C-CASA Ideation (of some nature) predict a C-CASA Act?

Charles M. Beasley, Jr., M.D.
Distinguished Lilly Scholar
Chief Scientific Officer, Global
Patient Safety

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How Big a Database

- n Assume 100 acts are necessary for reasonable analyses and that treatment within a disorder is irrelevant
 - Depression (18 studies; D:P – 2200:1551)
 - n Acts – 7 (0.19% = 7/3751)
 - n Patients needed: 53,586
 - Schizophrenia (3 studies; D:AC – 1796:810)
 - n Acts – 18 (0.69% = 18/2606)
 - n Patients needed: 14,478
 - Non-Psychiatric (D:P – 3420:2262)
 - n Acts – 0
 - n Patients needed: A **BIG** number

Database

n Contents

- Individual patient demographics: primary diagnosis, age, sex
- Treatment: placebo, named approved drugs, “investigational agent”
- By-visit C-CASA categories
- By-visit instrument individual item scores
- Other ?

Database

n Administration

- A Board, primarily constituted by an academic institution
 - n FDA membership
 - n Industry membership

n Access

- Academicians with project approval by the board
- Individual industry companies that contribute data and fund

FDA Contributions

- n Board institution selection
- n Funding
- n Assurance that all industry companies use a single instrument

NIH / VA Contributions

- n Board participation
- n Require that all funded treatment studies, in relevant diagnoses, include the instrument
- n Require that all funded treatment studies, in relevant diagnoses, contribute the data to the database

Academic Institution Contributions

- n One institution selected by FDA to administer the Board
- n Place all instruments that might be used in the public domain
 - It would then be much easier for FDA to mandate a given instrument
- n Contribute research using the database

Industry Contributions

- n Use a single instrument
- n Fund the database
- n Contribute studies to the database
- n Contribute research using the database

Why should Academicians or Individual Companies Share Secrets?

- n Without such a database, there will be only one entity with sufficient sample sizes to conduct relevant research