

Figure 1: Retrospective Criteria of Long-Term Treatment Response in Research Subjects with Bipolar Disorder

Name: _____ Date: _____

Drug: _____ Evaluated By: _____

Criterion A

The criterion A is used to determine an association between clinical improvement and the treatment. The rating should apply to the period of treatment considered adequate in duration and dosage. The illness activity should be judged by frequency, severity, and duration of episodes.

- 10 = Complete response, no recurrences in the course of adequate treatment, no residual symptoms, and full functional recovery
- 9 = Very good response, no recurrences, but the patient may have minimal residual symptoms (transient anxiety, sleep disturbance, dysphoria, irritability) not requiring any intervention
- 8 = Very good response. Illness activity reduced by more than 90%
- 7 = Good response. Illness activity reduced by 80 - 90 %
- 6 = Good response. Reduction in activity of illness by 65 - 80%
- 5 = Moderate response. Reduction in illness activity by 50 - 65%
- 4 = Moderate improvement. Reduction in illness activity by 35 - 50%
- 3 = Mild improvement. Reduction of illness activity by 20 - 35%
- 2 = Mild improvement. Reduction of illness activity by 10 - 20%
- 1 = Minimal improvement. Reduction of illness activity by 0 - 10%
- 0 = No change or worsening

A Criterion Score: _____

Criteria B

The criteria B are used to establish whether there is a causal relationship between clinical improvement and the treatment. Score 0, 1 or 2 points for each item:

B1: Number of episodes before the treatment:

- 0 = 4 or more episodes
1 = 2 or 3 episodes
2 = 1 episode

B1: _____

B2: Frequency of episodes before the treatment.

- 0 = Average to high, including rapid cycling
1 = Low, spontaneous remissions of 3 or more years on average
2 = 1 episode only, risk of recurrence cannot be established

B 2: _____

B3: Duration of the treatment.

- 0 = 2 or more years
1 = 1 - 2 years
2 = Less than 1 year

B 3: _____

B4: Compliance during period(s) of stability.

- 0 = Excellent, e.g. documented by drug levels in the therapeutic range
1 = Good, more than 80% levels in the therapeutic range
2 = Poor, repeatedly off treatment, less than 80% levels in the therapeutic range

B 4: _____

B5: Use of additional medication during the period of stability

- 0 = None except infrequent sleep medication (1 per week or less); no other mood stabilizers, antidepressants or antipsychotics for control of mood symptoms
1 = Low-dose antidepressants or antipsychotics as an "insurance", or prolonged use of sleep medication
2 = Prolonged or systematic use of an antidepressant or antipsychotic

B 5: _____

B Criteria Score: _____

Total Scale Score: _____
(Subtract B from A)