Screened (N=326)

Not randomized (n=159, 48.8%)
- Did not meet criteria (n=133, 40.8%)
- Adverse event (n=0)
- Other/administrative (n=26, 8.0%)

Randomized (n=167)

ITT (n=167)

Placebo (n=85)
- Withdrawn during double blind (n=24, 28.2%)
  - Adverse event (n=10, 11.8%)
  - Lack of compliance (n=1, 1.2%)
  - Lack of efficacy (n=5, 5.9%)
  - Lost to follow-up (n=3, 3.5%)
  - Other/administrative (n=5, 5.9%)
- Completed double blind (n=61, 71.8%)

Pregabalin 600 mg/d (n=82)
- Withdrawn during double blind (n=28, 34.1%)
  - Adverse event (n=14, 17.1%)
  - Lack of compliance (n=3, 3.7%)
  - Lack of efficacy (n=4, 4.9%)
  - Lost to follow-up (n=1, 1.2%)
  - Other (n=6, 7.3%)
- Completed double blind (n=54, 65.9%)

Entered open label (n=55, 64.7%)

Withdrawn during follow-up (n=24, 15.3%)
- Adverse event (n=5, 5.9%)
- Lack of compliance (n=1, 1.2%)
- Lost to follow-up (n=3, 3.5%)
- Other (n=4, 4.7%)

Completed follow-up (n=72, 84.7%)

Withdrawn during follow-up (n=15, 18.3%)
- Adverse event (n=7, 8.5%)
- Lack of compliance (n=2, 2.4%)
- Lost to follow-up (n=1, 1.2%)
- Other (n=6, 7.3%)

Completed follow-up (n=67, 81.7%)

Entered open label (n=49, 59.8%)

Withdrawn during follow-up (n=15, 18.3%)
- Adverse event (n=7, 8.5%)
- Lack of compliance (n=2, 2.4%)
- Lost to follow-up (n=1, 1.2%)
- Other (n=6, 7.3%)

Entered open label (n=49, 59.8%)