

“Characterization and Prediction of Placebo Responders in Peripheral Neuropathic Patients in a 4-week Analgesic Clinical Trial”



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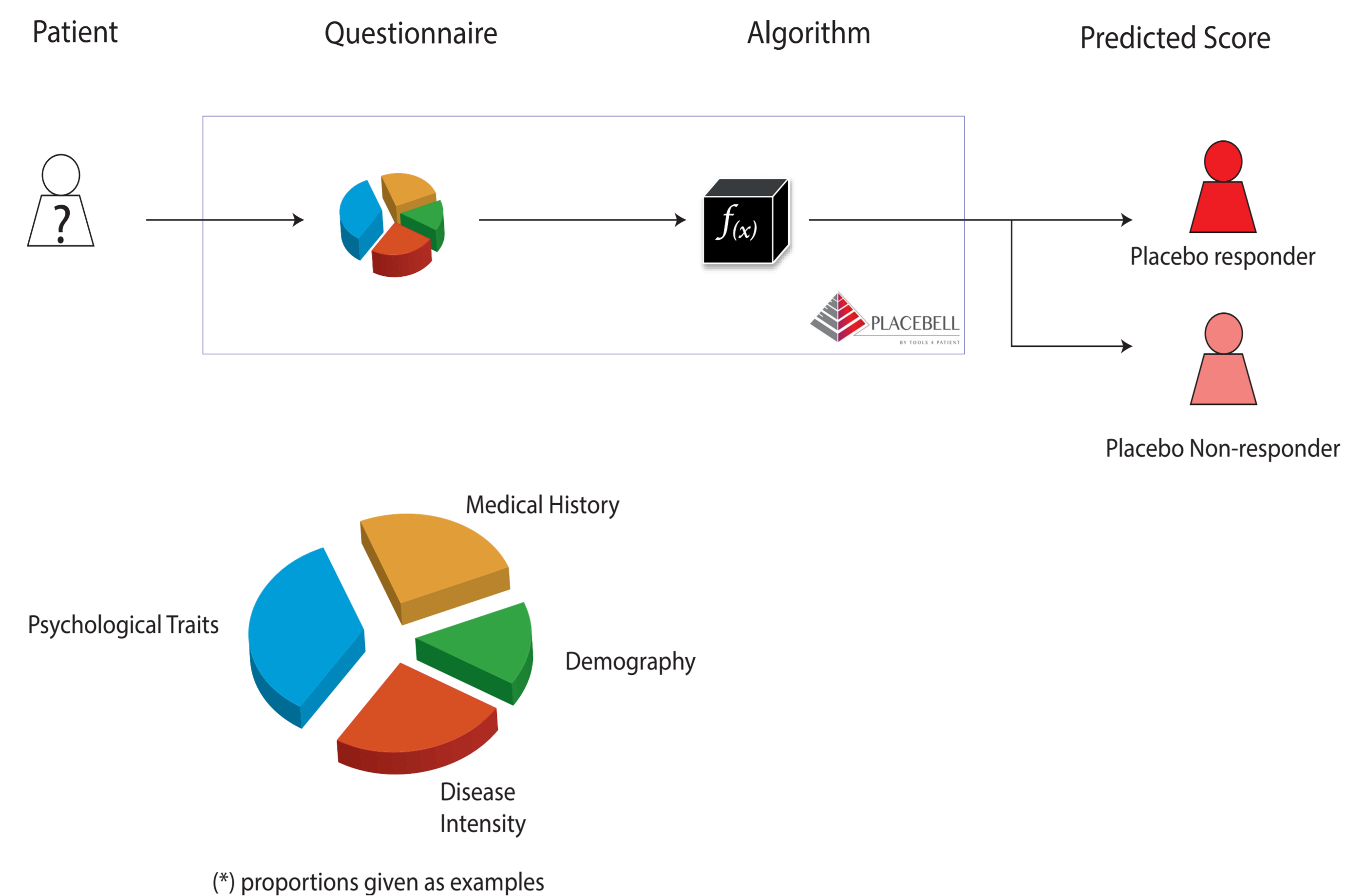
Introduction: Placebo problem

Placebo analgesia effect is a huge issue in clinical development:

- Increase with the time;
- Represent 2/3 of the drug response;
- Responsible for high attrition rate in Phase III.

Huge need for a characterization of the placebo responders.

Placebell© : Individual Characterization of Patient's Placebo Response



Predictive Model of Placebo Responder

Model predicting Placebo responder (Placebo responder or Placebo non responder):

- Good performance and stability;
- Sensitivity of 79% and specificity of 74%;
- Kuncheva index of 73 %.

Conclusions

Altogether, the above findings demonstrate for the first time:

- Baseline patients characteristics can be used to predict individual placebo responses;
- Such a tool may be used in RCTs to stratify patients within groups and thereby increase the assay sensitivity.

Methods

Single centre, patient-blind study

Placebo treatment b.i.d for 4 weeks as add-on therapy;
 Placebo presented as new investigational drug named T4P1001.

Patients main criteria for inclusion:

Chronic PNP diagnosed since at least 6 months (traumatic event, surgical procedure (excluding limb amputation), radiculopathy, post-herpetic or post-zoster neuralgia, diabetic polyneuropathy);
 Males or females; at least 18 years of age;
 Body weight greater than 40 kg and less than 120 kg; BMI between 19-31 kg/m² inclusive;
 DN4 score ≥ 4.

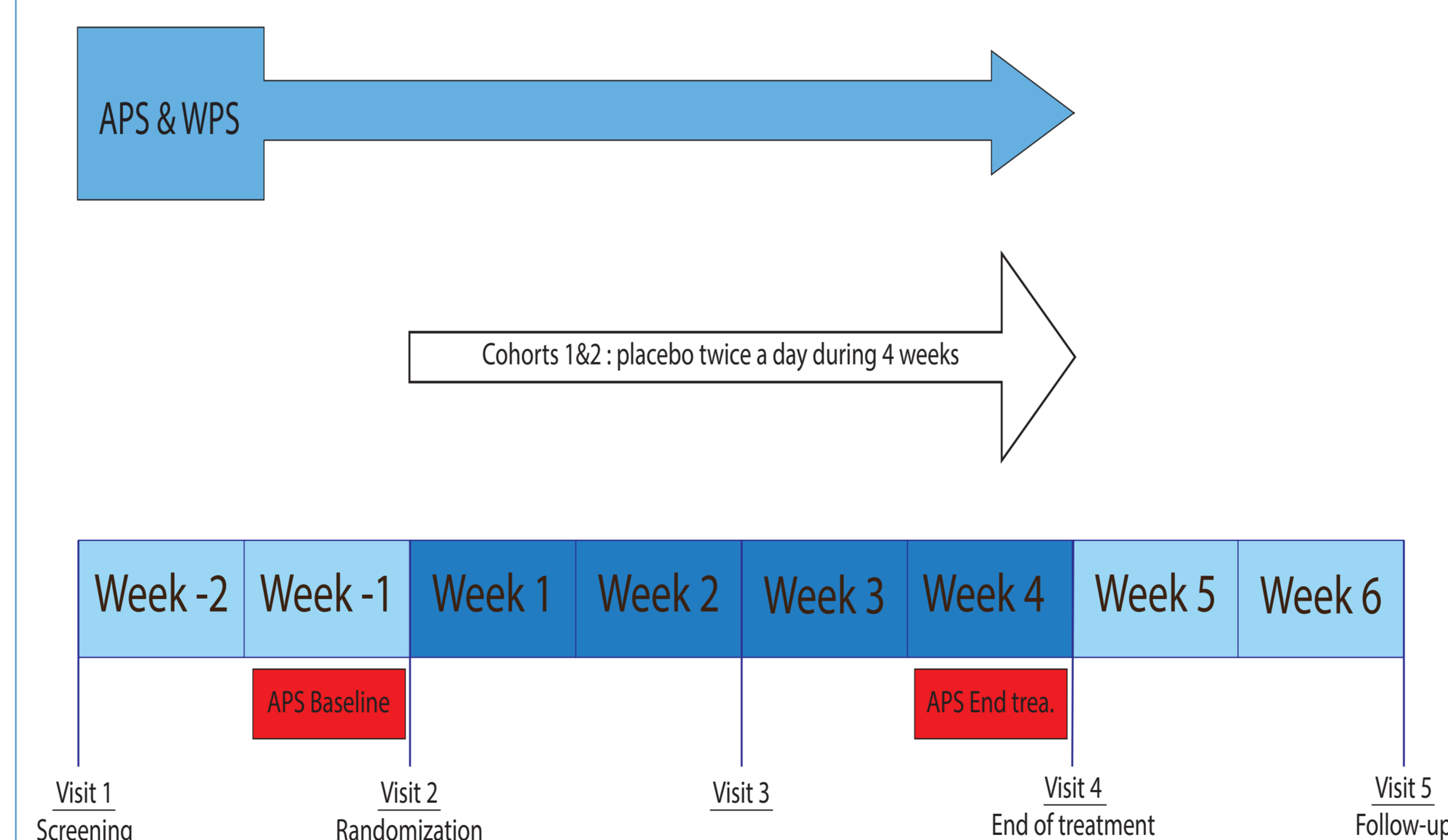
Patients main criteria for exclusion:

Neuropathic pain due to trigeminal neuralgia, central pain, complex regional pain syndrome and phantom limb pain;
 Patient changed his/her « regular therapy » in the last 4 months.

Psychological and Pain Evaluations

Big Five Inventory questionnaire, NEO Personality Inventory Revised, Belief in a Just World, Revised Life Orientation Test, Multidimensional Iowa Suggestibility Scale, Multidimensional Health Locus of Control Scale, Hospital Anxiety and Depression Scale, Expectation questionnaire, Pain Compliance Questionnaire, Average Pain Score, Worst Pain Score, Brief Pain Inventory short form, Investigator Global Assessment of Changes, Patient Global Assessment of Changes, DN4 questionnaire.

Neuropathic Patient Study Design



APS Endpoints	Placebo Responder	Placebo Non-Responder	All
N	12 (29.3%)	29 (70.7%)	41 (100%)
APS Week -1	5.2	5.3	5.3
APS Week 4	2.7	5.4	4.6
Reduction Mean P-Value	-48.2% <0.001	1.3% 0.487	-13.2% 0.003

