Figure 1. Final Conceptual Framework
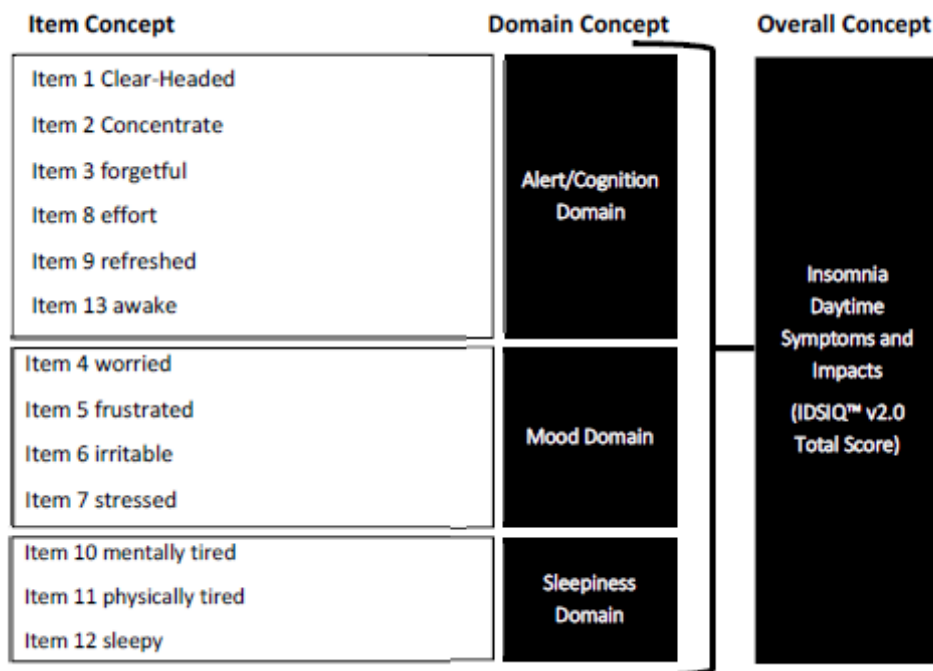

Table 1. Responsiveness of the IDSIQ™ [1] (Total Score) from Day 1 to Day 14/15 (LAP[2])

Assessment	n	Mean Change (SD)	95% CI	SES[3]	P-value[4]
Day 14/15					
PGI-C[5]					
Very much better	29	-46.72 (25.459)	(-56.41, -37.04)	-1.835	< 0.001
Moderately better	29	-29.69 (24.552)	(-39.03, -20.35)	-1.209	< 0.001
A little better	29	-22.24 (15.355)	(-28.08, -16.40)	-1.449	< 0.001
No change	14	-11.79 (19.248)	(-22.90, -0.67)	-0.612	0.0393
A little worse	5	-14.80 (10.545)	(-27.89, -1.71)	-1.403	0.0349
Moderately worse	0	N/A	N/A	N/A	N/A
Very much worse	1	N/A	N/A	N/A	N/A
PGA-S[6] Change from Day 1					
-4	7	-62.86 (22.490)	(-83.66, -42.06)	-2.795	< 0.001
-3	24	-42.29 (21.068)	(-51.19, -33.40)	-2.007	< 0.001
-2	24	-34.46 (23.690)	(-44.46, -24.45)	-1.455	< 0.001
-1	28	-18.04 (17.919)	(-24.98, -11.09)	-1.007	< 0.001
0	17	-14.18 (17.260)	(-23.05, -5.30)	-0.821	0.0038
+1	3	-8.33 (17.898)	(-52.79, 36.13)	-0.466	N/A
ISI[7] Change from Day 1					
-3	18	-50.50 (21.696)	(-61.29, -39.71)	-2.328	< 0.001

-2	37	-34.68 (25.076)	(-43.04, -26.32)	-1.383	< 0.001
-1	27	-14.30 (17.698)	(-21.30, -7.30)	-0.808	< 0.001
0	20	-23.75 (17.868)	(-32.11, -15.39)	-1.329	< 0.001
+1	1	0.00	N/A	N/A	N/A

Abbreviations: CI = confidence interval; FAS = full analysis population; IDSIQ[TM] = Insomnia Daytime Symptoms and Impacts Questionnaire[TM]; LAP = longitudinal analysis population; PGA-S = Patient Global Assessment of Severity; PGI-C = Patient Global Impression of Change; PRO = patient-reported outcome; SD = standard deviation; SES = standardized effect size.

[1] The IDSIQ[TM] is an 18-item PRO measure modified to 13 items after psychometric confirmation to the qualitative data. The instrument was collected daily, item responses ranged between 0 to 10 with higher scores representing more of the construct. Items 2, 3, 14 and 18 were reverse scored prior to summarizing.

[2] The LAP was used to calculate change scores at each visit and included subjects from the FAS who had available data at each study visit and had data at Day 1.

[3] Standardized effect sizes are judged as: small = 0.20, moderate = 0.50, and large = 0.80. This is specifically the standardized response mean, as the change in scores over time are divided by the change SD.[9]

[4] p-value significance level set at p < 0.05 and tests the difference in change score within groups.

[5] The PGI-C is a single item assessing the change in overall severity of daytime symptoms (eg, sleepiness) and impacts (eg, effort to perform daily activities) that the subject experienced over the preceding 7 days (recorded on Days 1, 8, and 15).

[6] The PGA-S is a single item that collected information on the subject's perception of their overall severity of daytime symptoms (eg, sleepiness) and impacts (eg, effort to perform daily activities) that the subject experienced over the preceding 7 days (recorded on Days 1, 8 and 15).

[7] The ISI is a 7-item PRO used to assess participants sleep patterns over the preceding 2 weeks (recorded on Day 1 and 14). The items evaluate the severity of sleep difficulties, satisfaction with sleep, interference of sleep problems on daytime activities and noticeability of sleep issues to others on quality of life. The assessment is on a 5-point scale (0 to 4) for each item and the composite score is obtained by summing the ratings on the seven items. Higher scores indicate worse insomnia symptoms, impairment, and quality of life.