Borderline across borderlines: Regional Variation in Who Enters Clinical Trials

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SUBMISSION DETAILS

What is the Methodological Question Being Addressed? The impact of regional, cultural or other geographic factors entering trials for borderline personality disorder (BPD) are unknown as they relate to the variability of presentation and diagnosis in clinical trials. Here we explore the potential differences in patterns of variability in BPD pathology and symptom severity in multiple, global placebo controlled trials of BPD.

Introduction BPD is marked by impairment in four domains: distorted perception of reality, emotional instability, impaired social relationships, and impulsivity. Prior academic reports indicate BPD is not culture bound and can be reliability diagnosed globally using the DSM-5 criteria1,2,3. Ideally subjects entering RCTs are representative of treatment seeking patients, but we are unaware of any data comparing subjects from different regions or language groups entering RCTs for BPD. Since cultural factors and health care systems vary widely and influence the representativeness of subjects entering research, comparative data on the severity and pattern of symptoms associated with BPD in of samples accrued in global clinical trials could be informative. We are, however, unaware of any data comparing subjects from different regions or language groups entering clinical trials for BPD.
We undertook a preliminary exploration of geographical variations across the DSM-5 diagnostic symptoms of BPD as measured by the ZAN-BPD1.

Methods This preliminary blinded dataset was drawn from multiple ongoing global placebo controlled clinical trials. Subjects were included if data was available indicating DSM-5 criteria were satisfied at screening and ZAN-BPD scores were available from screen and baseline assessments which included ZAN-BPD total score (range 0-36) as well as four sub-scale scores: affective disturbance (range 0-12), cognitive disturbance (range 0-8), impulsivity(range 0-8), disturbed relationships(range 0-8).
ANOVA will be employed to examine potential explanatory variables planned when the sample reaches at least n= 120 comparing groups with > 8 subjects.

Results To date we have ascertained data for 109 participants. All participants met DSM-5 criteria for BPD. We generated descriptive statistics compared ratings of the ZAN-BPD grand total score as well as the four sub-scales across six regions/language groups: United States, Western Europe, Eastern Europe, Japan, Pacific and Latin America.
Table 1 ZAN-BPD Mean scores for total and subscales.

	Mean Score (sd)				
Region (n)	Subscale score as % of total				
	ZAN_BPD total	Affective Disturbance	Cognitive Disturbance	Impulsivity	Disturbed

Relationships

Eastern Europe (5)	19.4 (3.51)	8.2 (0.84) 42.7%	3.2 (3.03) 16.5%	3.4 (1.52) 17.5%	4.6 (1.52) 23.7%
Japan (3)	13.3 (3.79)	6.3 (1.15) 47.5%	3.7 (0.58) 27.5%	0.67 (0.58) 5.0%	2.7 (1.53) 20.0%
Latin America (4)	15.8 (3.59)	7.0 (0.82) 44.4%	2.5 (0.58) 15.8%	1.8 (1.5) 11.1%	4.5 (1.91) 28.6%
United States (84)	17.7 (4.59)	7.2 (1.87) 40.9%	4.3 (1.72) 24.4%	2.1 (1.39) 11.8%	4.1 (1.53) 23.2%
Pacific (3)	17.3 (4.93)	7.7 (1.53) 44.3%	5.0 (1.0) 28.9%	1.3 (1.15) 7.7%	3.3 (2.31) 19.2%
Western Europe (10)	12.9 (2.6)	5.8 (0.79) 45.0%	2.9 (1.73) 22.5%	1.7 (1.16) 13.2%	2.5 (1.18) 19.4%

Conclusion Our preliminary findings suggest that symptom severity varies widely for subjects entering clinical trials for BPD across different regions, but the proportion of total score attributable to each subscale is similar across the groups. Interestingly, the largest raw ZAN-BPD total score difference and Affective Disturbance differences were observed for Eastern and Western Europe. Latin America and the United States, however, scored similarly.
We plan to present additional item-level data with larger sample size at the time of final submissions and plan further analysis to explore factors which may be associated with any significant variations found.

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Keywords

Keywords
Borderline Personality Disorder

Regional Variation
Cultural Variation

Guidelines I have read and understand the Poster Guidelines

Disclosures if applicable The authors are full time Employees of Signant Health

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