

Two Randomized, Double-Blind, Placebo-Controlled Trials of Adjunctive Troriluzole, a Novel Glutamate-Modulating Agent, in Obsessive-Compulsive Disorder

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CONCLUSIONS

- 1 The studies (NCT04641143 and NCT04693351) will investigate the efficacy and safety of troriluzole in patients with OCD
- 2 Demographic data reveal that the majority of randomized patients are women, enrolled in the USA, and White
- 3 The majority of self-reported Y-BOCS scores at baseline were in the severe range (24-27), with the highest scores in participants 40-59 years of age
- 4 The proportion of participants reporting more severe Y-BOCS scores increases directly with age
- 5 We found no association between participants' self-reported Y-BOCS score at baseline and the number of years of OCD history

Disclosures: MSO: employed by and holds stock/stock options in Biohaven. LM: employed by and holds stock/stock options in Biohaven. AR: employed by and holds stock/stock options in Biohaven. DS: employed by and holds stock/stock options in Biohaven. TM: employed by and holds stock/stock options in Biohaven. LD: employed by and holds stock/stock options in Biohaven, VC: employed by and holds stock/stock options in Biohaven, AM: employed by and holds stock/stock options in Biohaven.

References: 1. Pittenger C, Bloch MH, Wasylink S, et al. Riluzole augmentation in treatment-refractory obsessive-compulsive disorder. *J Clin Psychiatry*. 2015;76(08):1075-1084. 2. Brennan BP, Rauch SL, Jensen JE, Pope HG Jr. A critical review of magnetic resonance spectroscopy studies of obsessive-compulsive disorder. *Biol Psychiatry*. 2013;73(1):24-31. 3. Grant P, Song JY, Swedo SE. Review of the use of the glutamate antagonist riluzole in psychiatric disorders and a description of recent use in childhood obsessive-compulsive disorder. *J Child Adolesc Psychopharmacol*. 2010;20(4):309-315.

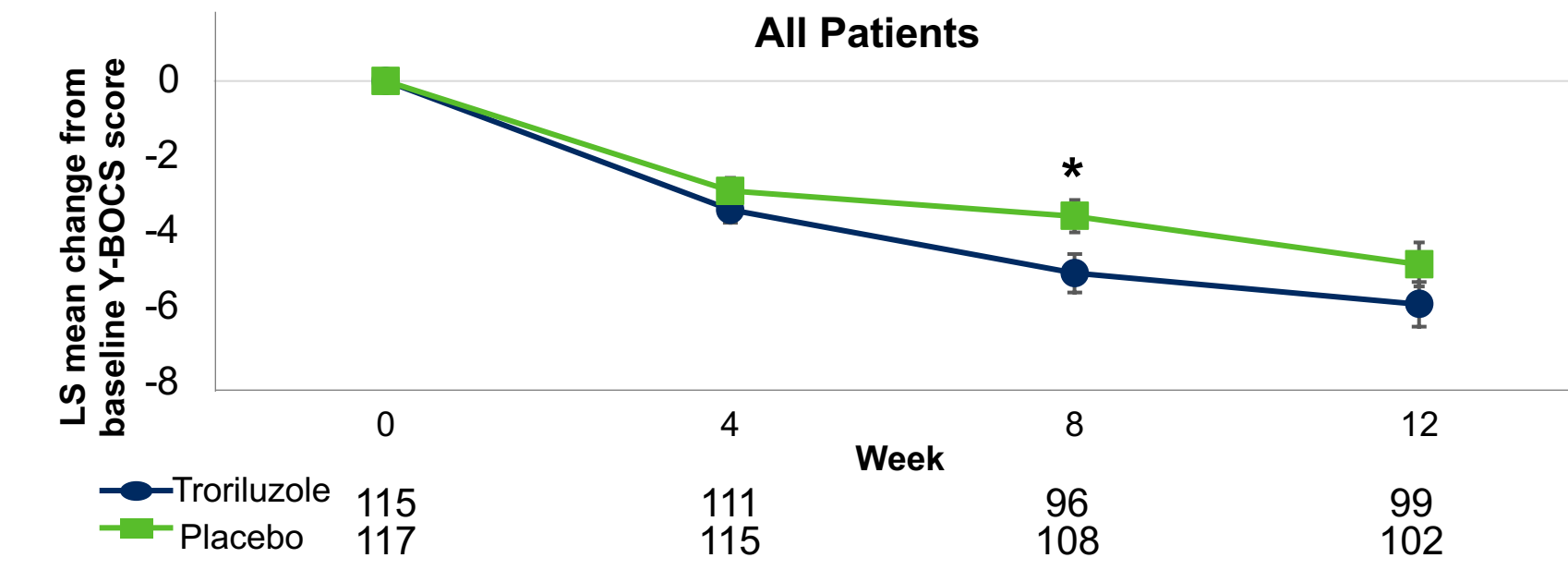
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BACKGROUND

- ▶ Dysregulation of glutamate, specifically within the cortico-striatal-thalamic pathway, has been implicated in obsessive-compulsive disorder (OCD)
- ▶ Troriluzole, a novel glutamate-modulating agent, may normalize synaptic glutamate levels and thus improve OCD symptoms
- ▶ A phase 2 proof-of-concept study in adult patients with OCD revealed a consistent numerical treatment benefit at each time point of troriluzole 200 mg treatment compared to placebo when added to standard-care SSRI/SNRI medications
- ▶ The magnitude of change in Yale–Brown Obsessive Compulsive Scale (Y-BOCS) scores indicated a clinically meaningful benefit



Phase 2 Proof-of-Concept Study of Y-BOCS Score Change From Baseline

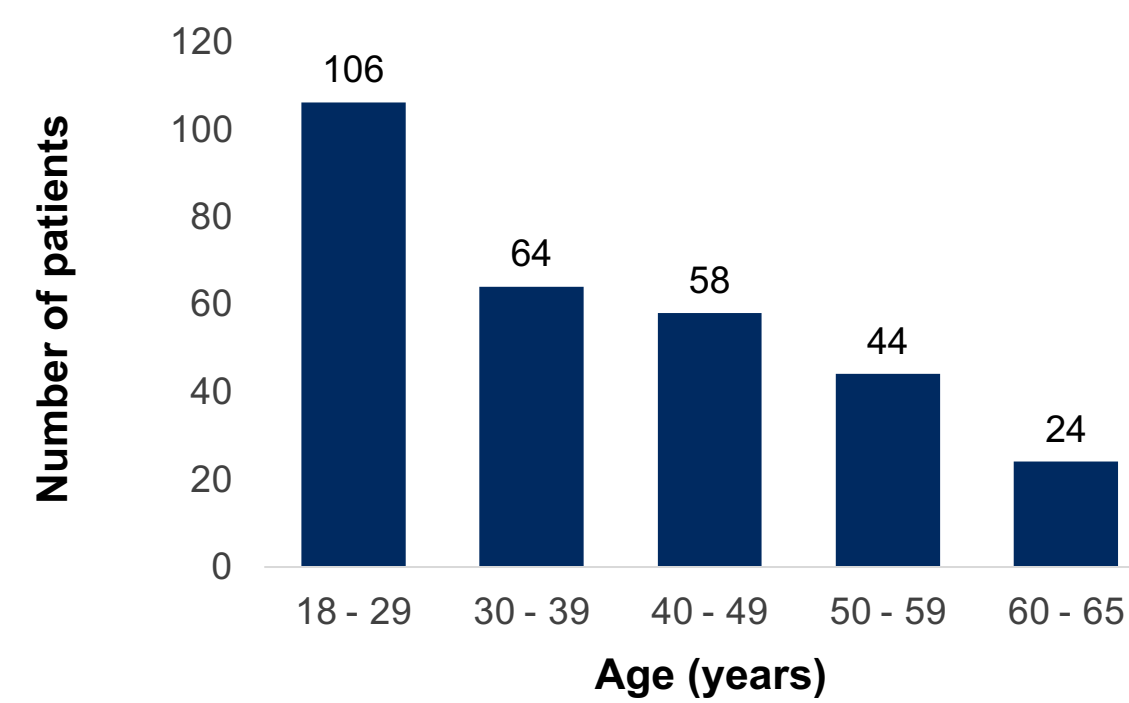
*Least Squares (LS) mean Y-BOCS score change in the primary analysis population was significant at Week 8 ($P = .04$) but not significant for the primary endpoint at Week 12 ($P = .22$). The panel below the figure shows the number of patients contributing data at each time point.

RESULTS

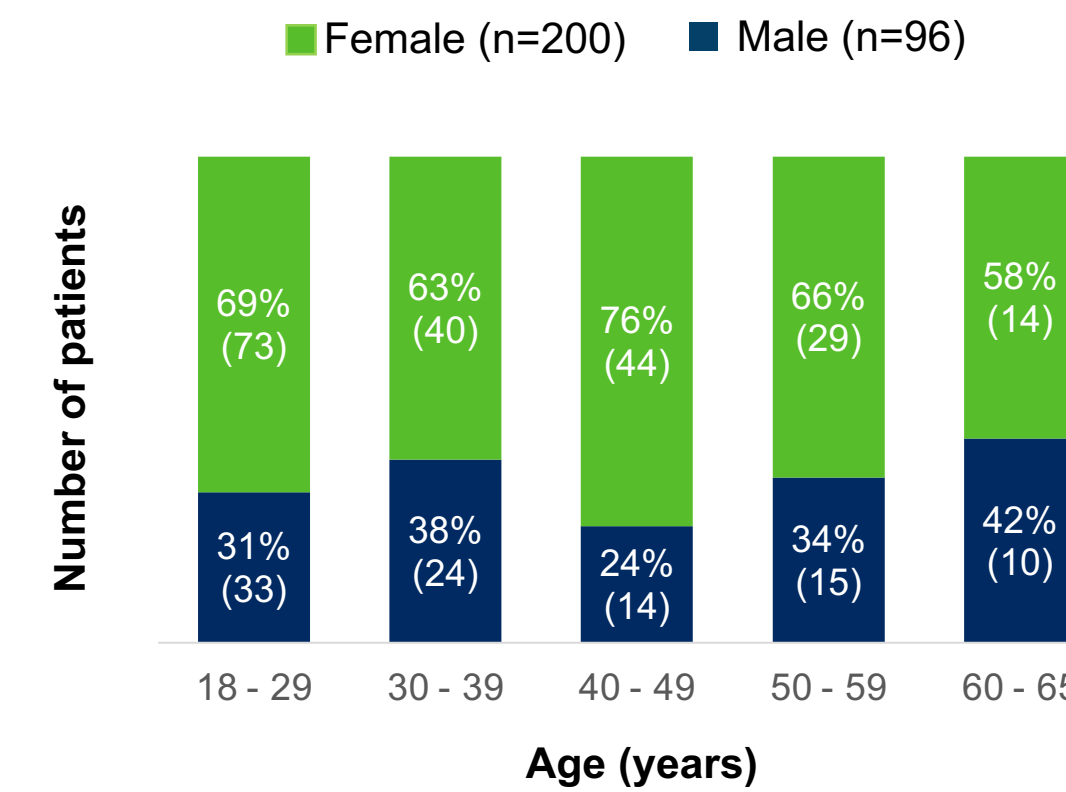
- ▶ Analysis of demographic data on patients randomized as of August 1, 2022 (N = 296) reveals that most patients (68%) are women
- ▶ Patients 18-39 years of age comprise 57% of those randomized
- ▶ The ranges of patients' baseline Y-BOCS scores were 22-23 (12%), 24-27 (41%), 28-31 (31%), and 32-40 (16%)
- ▶ The majority of patients (55%) reported 2-10 years of OCD history, while 20% reported 11-20 years of OCD history and 17% reported ≥ 21 years of OCD history
- ▶ A greater proportion of males than females reported 2-5 years or ≥ 21 years of OCD history

PATIENT DEMOGRAPHICS

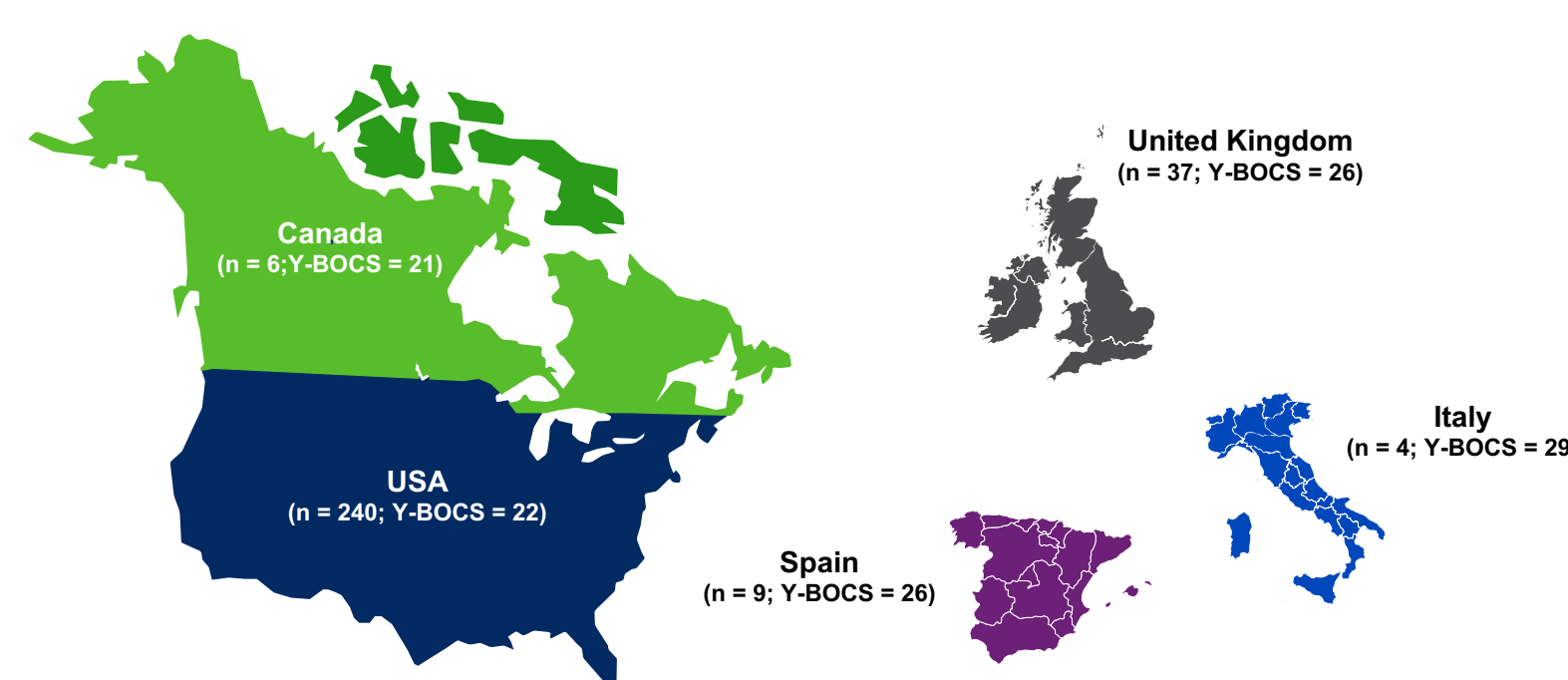
Frequency Distribution by Age Groups



Age Distribution by Gender



Geographic Location of Patient Enrollment (No. Enrolled; Mean Y-BOCS Score)



Race Distribution Among Patients

Race	Patients (%)
American Indian or Alaska Native	0.3%
Asian	3.4%
Black or African American	4.1%
Not reported	0.3%
Other	3.0%
White	88.9%

OBJECTIVE

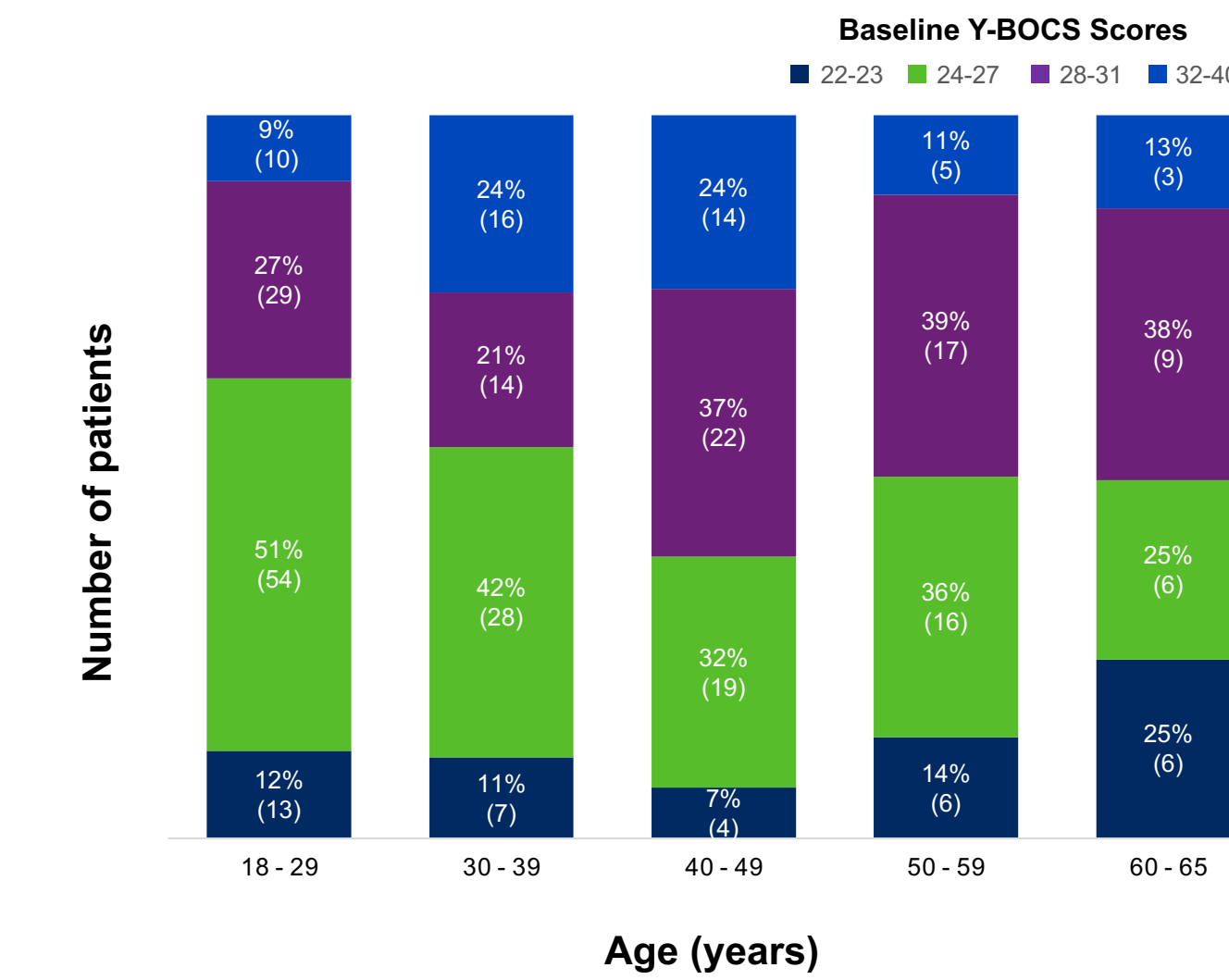
- ▶ Describe the design, scientific rationale, and demographic characteristics of the studies

METHODS

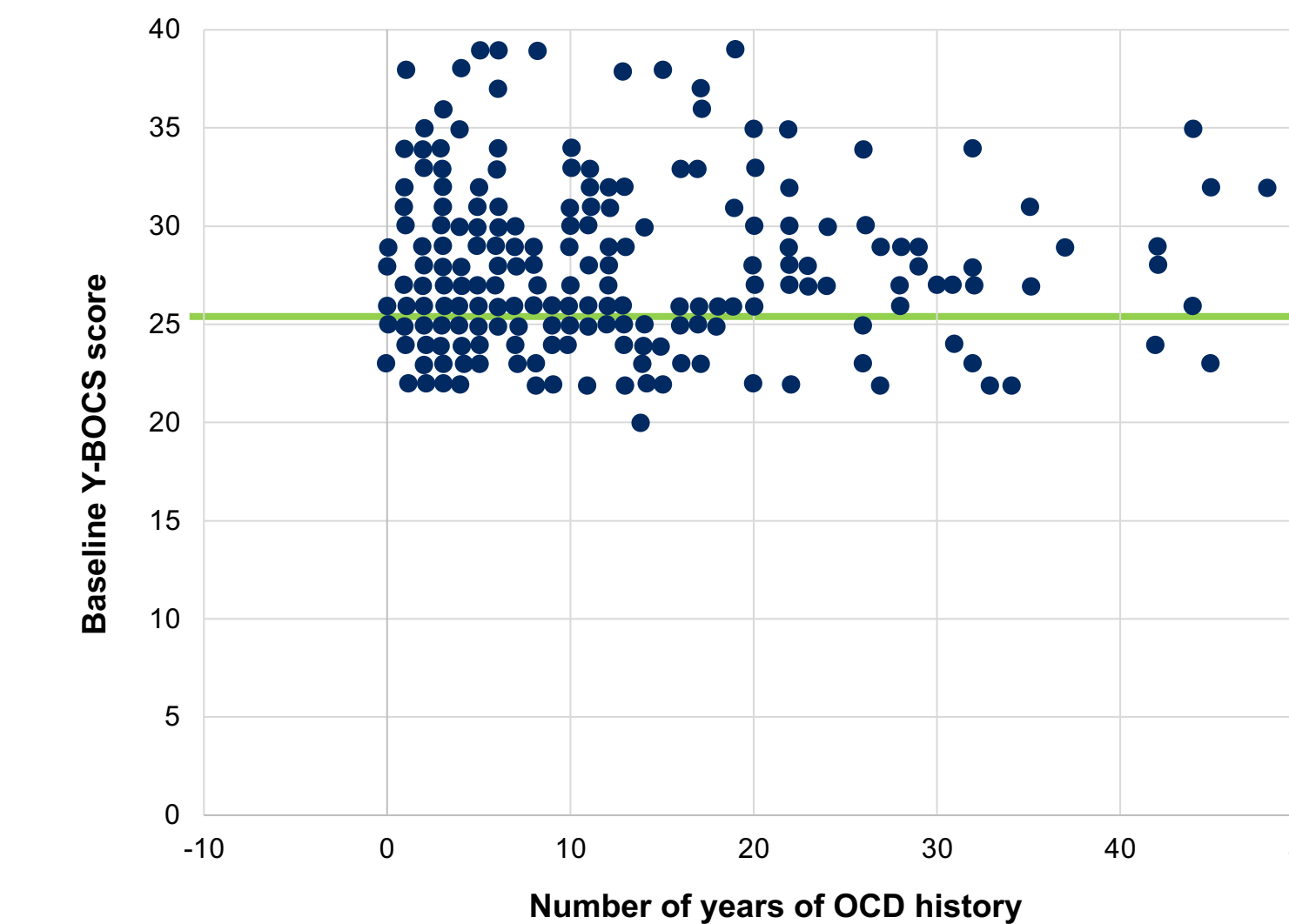
- ▶ Two identical studies are being conducted, 1 with patients from the USA and 1 with patients from the USA, Canada, the United Kingdom, Spain, Italy, and the Netherlands
- ▶ Each study is a 10-week, randomized, double-blind, placebo-controlled, parallel group design testing troriluzole 280 mg in 700 individuals
- ▶ Patients must have a diagnosis of OCD for ≥ 1 year with inadequate response to an ongoing standard-care medication, as defined by a Y-BOCS score ≥ 22 at screening and baseline
- ▶ The primary endpoint is change in Y-BOCS score from baseline to Week 10
- ▶ The studies began enrollment in December 2020 and are ongoing

BASELINE CHARACTERISTICS

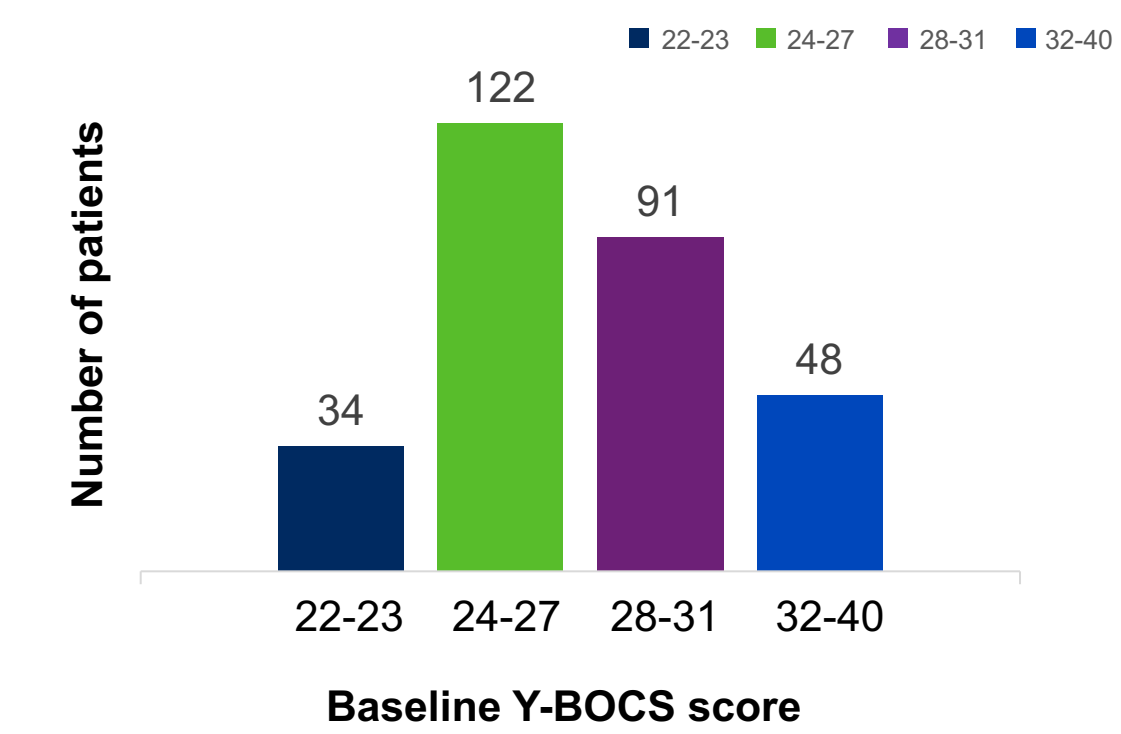
Baseline Y-BOCS Scores by Participant Age



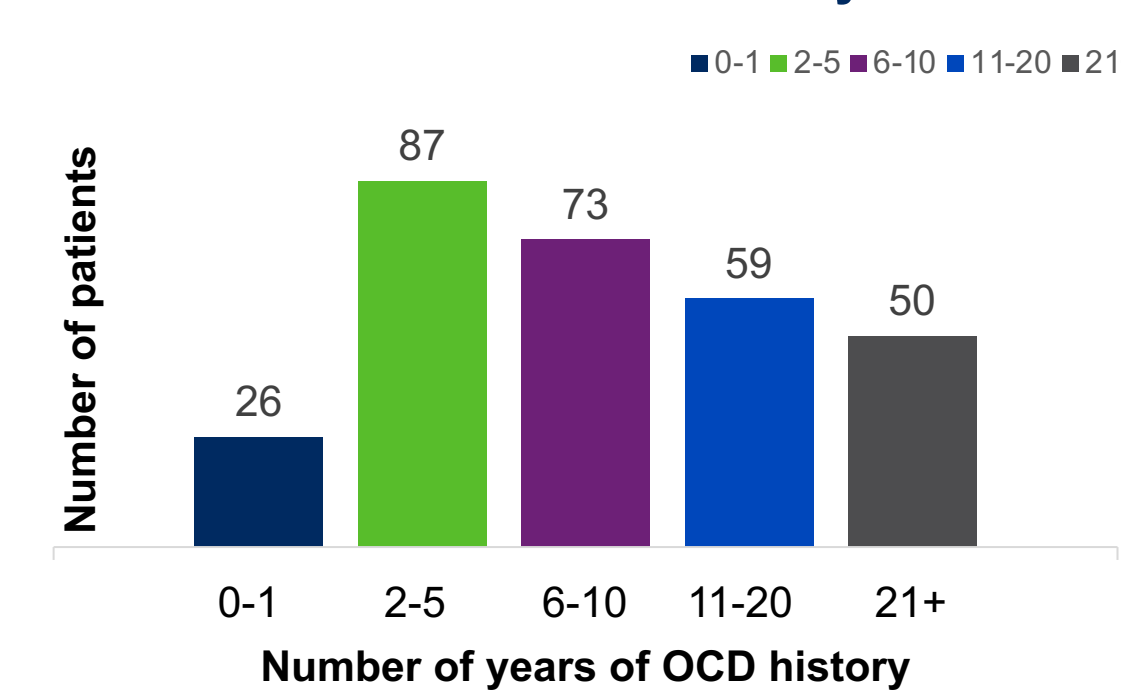
Scatterplot of Reported Years of OCD History and Baseline Y-BOCS Score



Frequency Distribution of Baseline Y-BOCS Scores



Frequency Distribution of Reported Years of OCD History



Reported Years of OCD History by Sex

