

# A Study to Learn More About the Effects and Long-Term Safety of BIIB141 (Omaveloxolone) in Participants With Friedreich's Ataxia Aged 2 to 15 Years Old (BRAVE)

NCT06953583

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Status	RECRUITING
Phase	Phase 3
Sponsor	Biogen
Enrollment	255 participants

## Key Eligibility Criteria

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### Inclusion (2)

- Diagnosed with genetically confirmed Friedreich's Ataxia (FA), i.e., homozygous for guanine-adenine-adenine (GAA) repeat expansion in intron-1 of the frataxin gene, or GAA repeat expansion in 1 allele and with point mutations or deletions, or other non-GAA expansion mutations in the other allele.
- Symptomatic for FA as confirmed by clinician assessment. a. Children 7 to < 16 years must also have an upright stability score (USS) score of 10 to d 34 at baseline

### Exclusion (11)

- Glycosylated hemoglobin A1C (HbA1c) > 11%
- B-type natriuretic peptide (BNP) > 200 picograms per milliliter (pg/mL) at screening
- Ejection fraction (EF) < 40% \[based on echocardiogram (ECHO) performed at screening visit\]
- Clinically significant cardiac disease except mild to moderate cardiomyopathy
- Part 2 OLE: Eligibility criteria:  
... and 6 more (see full listing online)

## Locations (34 total)

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UCLA Neurology Outpatient Clinic at Westwood, Los Angeles, California, United States  
Norman Fixel Institute for Neurological Diseases UF Health, Gainesville, Florida, United States  
USF Health Morsani College of Medicine Department of Neurology, Tampa, Florida, United States  
... and 31 more locations