

# A Study to Investigate the Efficacy and Safety of Fitusiran Prophylaxis in Male Participants Aged 1 to Less Than 12 Years With Hemophilia A or B

NCT07285460

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Status	RECRUITING
Phase	Phase 3
Sponsor	Sanofi
Enrollment	85 participants

## Key Eligibility Criteria

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### Inclusion (16)

- Participants not previously exposed to fitusiran are eligible to be included in the study only if all of the following criteria apply:
- Participant must be 1 to <12 years of age at the time of enrollment.
- Participants must have severe hemophilia A or B (FVIII <1% or FIX d2%) as evidenced by a central laboratory measurement at screening or documented medical record evidence.
- Participants must meet inhibitor or non-inhibitor status as defined below:
- Inhibitor:  
... and 11 more (see full listing online)

### Exclusion (25)

- Participants not previously exposed to fitusiran are excluded from the study if any of the following criteria apply:
- Known co-existing bleeding disorders other than hemophilia A or B.
- Presence of clinically significant liver disease.
- History of antiphospholipid antibody syndrome.
- History of arterial or venous thromboembolism, unrelated to an indwelling venous access  
... and 20 more (see full listing online)

## Locations (18 total)

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The Lusk Orthopaedic Institute for Children- Site Number : 8400013, Los Angeles, California, United States  
The Center for Inherited Blood Disorders- Site Number : 8400009, Orange, California, United States  
Cure 4 The Kids Foundation- Site Number : 8400001, Las Vegas, Nevada, United States  
... and 15 more locations