

# BElumosudil for Bronchiolitis Obliterans Prevention/Therapy (BE-BOP)

NCT05922761

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 2
<b>Sponsor</b>	Dana-Farber Cancer Institute
<b>Enrollment</b>	45 participants

## Key Eligibility Criteria

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### Inclusion (25)

- Diagnosis of BOS after HCT using pulmonary function testing, per the NIH diagnostic criteria<sup>17</sup> OR the Atypical BOS criteria<sup>33</sup>  
3.1.2.1 NIH Diagnostic Criteria for BOS. All of the following must be met:
- FEV1/VC  $\leq$  0.7 or  $\leq$ 5th percentile of predicted (FEV1 = Forced Expiratory Volume in 1 second; VC = Vital Capacity (either FVC, Forced Vital Capacity, or SVC, Slow Vital Capacity, whichever is greater))
- FEV1  $\leq$ 75% of predicted with  $\geq$  10% absolute decline over less than 2 years. FEV1 should not correct to  $\geq$ 75% of predicted with albuterol, and the absolute decline for the corrected values should still remain  $\geq$  10% over 2 years.
- Absence of active infection in the respiratory tract, documented with investigations directed by clinical symptoms, such as chest radiographs or computed tomographic scans or microbiologic cultures (sinus aspiration, upper respiratory tract viral screen, sputum culture, bronchoalveolar lavage).
- One of the two supporting features of BOS:  
... and 20 more (see full listing online)

### Exclusion (6)

- Participants who have received prior therapy specifically for BOS. Therapy for cGVHD in the absence of BOS is permissible.
- Prior exposure to belumosudil.
- Participants who are receiving any other investigational immunosuppressive agents for cGVHD.
- Presence of an active uncontrolled infection. An active uncontrolled infection is defined as hemodynamic instability attributable to sepsis or new symptoms, worsening physical signs, or radiographic findings attributable to infection. Persistent fever without signs or symptoms will not be interpreted as an active uncontrolled infection.
- Known human immunodeficiency virus infection. Interactions between belumosudil and anti-retroviral agents have not been established.  
... and 1 more (see full listing online)

## Locations (5 total)

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Dana-Farber Cancer Institute, Boston, Massachusetts, United States  
Boston Children's Hospital, Boston, Massachusetts, United States  
Brigham and Women's Hospital, Boston, Massachusetts, United States  
... and 2 more locations

<https://clinicaltrials.gov/study/NCT05922761>

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