

L-PVDOMICS PROTOCOL Changes from Version 1.1 September 10, 2019 for Version 1.2 February 21, 2020

3.2 Exclusion criteria

Definition of Level of participant is given in Section 4.1.

Participant Level 1:

- [Previously received a heart and/or lung transplant](#)
- In the clinician's opinion, too ill to perform L-PVDOMICS testing even if limited testing. Participants who withdrew from the parent PVDOMICS study
- Pregnant or nursing
- Concurrent participation in any [pulmonary hypertension](#) investigational drug study or other [blinded placebo-controlled drug](#) clinical trial

Deleted: Transplant other than heart or lung

Participant Level 2:

- [Previously received a heart and/or lung transplant](#)
- Participants who withdrew from the parent PVDOMICS study

Deleted: Transplant other than heart or lung

Participant Level 3:

- Participants who withdrew from the parent PVDOMICS study

4.1. Study Visit

Level 3 Participation

Any person not agreeing to participate at Level 1 or 2 can participate at Level 3. For this level, a medical record review will collect clinically available data (including RHC, echocardiogram, cardiac MRI, CPET, PFT, sleep study, chest CT scan, ECG) within 3 months (either side) of L-PVDOMICS enrollment date. If the participant had a [heart and/or lung transplant](#) or died since the parent study, the date of transplant or death will be documented per the parent PVDOMICS protocol and the medical record review will collect data within 3 months prior to the transplant or death date [except when the transplant or death occurred before 6 months after the parent study enrollment. In this case, all clinically available data should be collected from after the parent study up to the transplant or death.](#)