The Trial Innovation Network is assisting Dr. Lew Romer from Johns Hopkins University with their proposal titled: **Trial of Mono- vs. Dual Therapy for Children with Pulmonary Arterial Hypertension, Kids MoD PAH.**

- Therapeutic Area: Pediatric Cardiology
- Funding Source / FOA: National Heart, Lung, and Blood Institute (NHLBI)
- Funding Status: Funded (study funded)
- Expected Number of Sites: 12
- Number of Sites yet to be Identified: 2
- Study Population Size: 100

The **Kids MoD PAH** study team is requesting sites' assistance in identifying a site-level investigator to collaborate on the **Kids MoD PAH**.

Study Synopsis:
Our central hypothesis is that initiation of combination therapy with sildenafil and bosentan at the time of PAH diagnosis will improve outcomes at 1 year as measured by WHO Functional Class (FC) in comparison with the use of sildenafil therapy alone.

Study Design:
A Phase III, randomized, open label trial to compare the safety and efficacy of first-line combination therapy (sildenafil and bosentan) to first-line monotherapy (sildenafil alone) in 100 newly diagnosed pedatric subjects ages ≥3 months to <18 years with WSPH Groups 1 or 3 pulmonary arterial hypertension (PAH), WHO FC II or III symptoms, and who have not been previously treated with long-term PAH drug therapy.

Ideally the site investigators will have:

- Pediatric cardiologist, pulmonologist, neonatologist or intensivist
- Actively treating patients with pediatric pulmonary hypertension

In addition to the standard criteria needed for sites to qualify for participation, this study also requires the following qualifications:

1. Designated single site PI interested in pediatric pulmonary hypertension, designated study coordinator
2. Ability to enroll participants inpatient and outpatient settings (i.e., PICU, NICU, outpatient clinics)
3. Pediatric echocardiography and cardiac catheterization facilities and expertise
4. Adhere to 90-day accelerated start up, and can rely on external IRB

You can contact Mugisha Niyibizi (mugisha.niyibizi@emory.edu) for a more detailed protocol for this study and to develop the items needed to respond to this request.