<table>
<thead>
<tr>
<th>Study Name/Organ</th>
<th>Description</th>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
<th>Contact/PI</th>
</tr>
</thead>
</table>
| ASSET           | A phase 2 study to evaluate subcutaneous abatacept vs. placebo in diffuse cutaneous systemic sclerosis – a double-blind, placebo-controlled, randomized controlled trial | • Diagnosis of SSC defined by ACR criteria  
• dcSSc as defined by LeRoy and Medsger  
• Disease duration of ≤ 36 months (defined as time from the first non-Raynaud phenomenon manifestation)  
• For disease duration of ≤ 18 months  
• *10 and ≤ 25 mRSS units at the screening visit  
• For disease duration of >18-36 months  
• *≥ 15 and ≤ 45 mRSS units at the screening visit and one of the following:  
  • **Increase ≥ 3 in mRSS units compared with the last visit within previous 1–6 months  
  • **Involvement of one new body area with ≥ 2 mRSS units compared with the last visit within the previous 1–6 months  
  • **Involvement of two new body areas with ≥ 1 mRSS units compared with the last visit within the previous 1–6 months  
  • **Presence of 1 or more Tendon Friction Rub | • 1. Rheumatic disease other than dcSSc; it is acceptable to include patients with fibromyalgia and scleroderma-associated myopathy  
• 2. lcSSc or sine scleroderma at the screening visit  
• 3. Major surgery (including joint surgery) within 8 weeks prior to screening visit  
• 4. Infected ulcer prior to randomization  
• 5. Treatment with any investigational agent within ≤ 4 weeks (or 5 half-lives of the investigational drug, whichever is longer) of the baseline visit  
• 6. Severe (MRSS 3+) skin on the inner aspects of thighs, upper arms, and abdomen  
• 7. Previous treatment with cell-depleting therapies, including investigational agents, including but not limited to, CAMPATH, anti-CD4, anti-CD5, anti-CD3, anti-CD19, and ABA  
• 8. Pulmonary disease with FVC ≤ 50% of predicted, or DLCO (uncorrected for hemoglobin) ≤ 40% of predicted at the screening visit | Jennelle Shaw  
734-936-4555  
jdsh@med.umich.edu |
|                |             |                    |                   | PI: Dr. Khanna |
## SCLERODERMA PROGRAM

**ASC01 Rituximab NIH**

**Randomized, Double-blind, Placebo-Controlled, Phase II Multicenter Trial of a Monoclonal Antibody to CD20 (Rituximab) for the Treatment of Systemic Sclerosis-Associated Pulmonary Arterial Hypertension (SSc-PAH)**

- Ages 18 – 75
- Diagnosis of SSc-PAH within the past 5 years
- Mean PVR of >3 wood units
- NYHA Functional Class II, III, or IV
- Must be able to maintain an O2 saturation of ≥90%
- Must be treated with background medical therapy for PAH
- PAH >5 years
- Measurement of meanPAP >25mmHg by Right Heart Catheterization
- Persistent hypotension with systolic blood pressure <90mmHg
- History of CAD, or any significant ventricular tachy-arrhythmia, stent replacement, CABG, or MI within 3 years of randomization
- Treatment of a DMARD within 4 weeks prior to randomization.
- Prior treatment with rituximab or exposure to any lymphocyte depleting agent

---

**ASC01 Rituximab NIH**

**Randomized, Double-blind, Placebo-Controlled, Phase II Multicenter Trial of a Monoclonal Antibody to CD20 (Rituximab) for the Treatment of Systemic Sclerosis-Associated Pulmonary Arterial Hypertension (SSc-PAH)**

- Ages 18 – 75
- Diagnosis of SSc-PAH within the past 5 years
- Mean PVR of >3 wood units
- NYHA Functional Class II, III, or IV
- Must be able to maintain an O2 saturation of ≥90%
- Must be treated with background medical therapy for PAH
- PAH >5 years
- Measurement of meanPAP >25mmHg by Right Heart Catheterization
- Persistent hypotension with systolic blood pressure <90mmHg
- History of CAD, or any significant ventricular tachy-arrhythmia, stent replacement, CABG, or MI within 3 years of randomization
- Treatment of a DMARD within 4 weeks prior to randomization.
- Prior treatment with rituximab or exposure to any lymphocyte depleting agent

---

**Jennelle Shaw**
734-936-4555
jdsh@med.umich.edu

**PI: Dr. Khanna**
**Co-PI: Dr. McLaughlin**
A Randomized, Double-Blind, Placebo-Controlled Phase II Study to Investigate the Efficacy and Safety of Riociguat in Patients With Diffuse Cutaneous Systemic Sclerosis (dcSSc)

- Systemic sclerosis, as defined by ACR/EULAR (American College of Rheumatology/European League Against Rheumatism) 2013 criteria
  - dcSSc (diffuse cutaneous systemic sclerosis) according to the LeRoy criteria
  - Disease duration of ≤ 18 months (defined as time from the first non-Raynaud's phenomenon manifestation)
  - ≥ 10 and ≤ 22 mRSS (modified Rodnan skin score) units at the screening visit
  - FVC (forced vital capacity) ≥ 45% of predicted at screening
  - DLCO (diffusion capacity of the lung for carbon monoxide) ≥ 40% of predicted (hemoglobin-corrected) at screening
- Limited cutaneous SSc (systemic sclerosis) at screening
- Major surgery (including joint surgery) within 8 weeks prior to screening
- Left ventricular ejection fraction < 40% prior to screening
- Diagnosed PAH (pulmonary arterial hypertension) as determined by right heart catheterization
- Pulmonary disease with FVC < 45% of predicted or DLCO (hemoglobin-corrected) < 40% of predicted at screening

Aaron Rankin 734-936-4555 rankina@med.umich.edu
PI: Dr. Schiopu